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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH
CENTRAL DIVISION

In re Myriad Genetics, Inc. Securities Litigation	**Case No. 2:19-cv-00707-DBB** **Judge David B. Barlow** **AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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Court-appointed Lead Plaintiff Los Angeles Fire and Police Pensions ("Los Angeles" or "Lead Plaintiff"), by its undersigned attorneys, brings this action under Sections 10(b), 20(a) and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), and U.S. Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, on behalf of itself and all other similarly-situated purchasers of the common stock of Myriad Genetics, Inc. ("Myriad" or the "Company") from August 9, 2017 until February 6, 2020, inclusive (the "Class Period").

Court-appointed Lead Plaintiff Los Angeles is dedicated to administering the defined benefit retirement plan for all sworn (Fire, Police and certain Port Police and Airport Police) employees of the City of Los Angeles. In that role, Los Angeles provides service to approximately 13,500 active members and 13,000 retirees and beneficiaries. Los Angeles alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based on, among other things, the independent investigation of Court-appointed Lead Counsel Bernstein Litowitz Berger & Grossmann LLP. This investigation included a review and analysis of: (i) Myriad's public filings with the SEC; (ii) public reports and news articles; (iii) research reports by securities analysts; (iv) economic analyses of securities movement and pricing data; (v) transcripts of Myriad's investor calls; (vi) consultations with relevant experts; (vii) interviews with former Myriad employees; and (viii) other publicly available material and data identified herein. Lead Counsel's investigation into Los Angeles's factual allegations is continuing, and many of the facts supporting its allegations are known only to the Defendants or are exclusively within their custody or control. Los Angeles believes that further substantial evidentiary support will exist for its allegations after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This case arises from misstatements and omissions made to investors by Myriad, a genetic test manufacturer, and its most senior executives about the Company's two most significant products during the Class Period: (i) GeneSight, a test that purports to predict how a patient will react to medication, which analysts hailed as Myriad's single "most important growth driver"; and (ii) Myriad's hereditary cancer tests, a bulwark of Myriad's business that were responsible for more than half of all Company-wide revenue during the Class Period.

2. As detailed herein, Myriad scientists internally discussed with senior Company personnel, including Defendants, that key elements of Myriad's critical GeneSight test lacked meaningful scientific and clinical support. Nevertheless, throughout the Class Period, Defendants publicly assured investors that GeneSight was "clinically proven to enhance medication selection" and, in particular, touted the results of its "landmark" clinical study of GeneSight, called GUIDED, as providing strong support for the product's effectiveness. None of these statements were true, as investors were ultimately shocked to learn through a series of disclosures.

3. These disclosures included most significantly Myriad's August 2019 admission that it had been forced to withdraw key parts of the GeneSight test and that the FDA had demanded the Company make commercially devastating changes to the rest of it. Just a few months later, in November 2019, investors received another shock when they learned that Myriad had been overstating revenue attributable to its hereditary cancer testing – the revenue stream that was to act as the Company's lifeline while it worked to grow GeneSight. The Class Period ends with the February 6, 2020 resignation of the chief architect and spokesperson behind Myriad's claims that its genetic tests were scientifically proven, former CEO and Defendant Mark Capone.

4. Unlike pharmaceutical drugs or medical devices, genetic laboratory tests, like those manufactured by Myriad, are not subject to a rigorous FDA approval process designed to

ensure their efficacy and safety before they introduce the tests to the market. Instead, it is incumbent on the test manufacturers to ensure that they are selling tests that offer scientifically valid results to patients.

5. According to Myriad, the GeneSight test was "clinically proven to enhance medication selection" to help doctors determine how patients would respond to different types of drugs, including most significantly: (i) analgesic drugs used to treat pain; (ii) drugs used to treat attention deficit hyperactivity disorder ("ADHD"); and (iii) psychotropic drugs used to treat major depressive disorder.[1] In truth, GeneSight lacked clinical proof to support those claims.

6. As discussed below, on August 13, 2019, Myriad admitted that the scientific evidence available to the Company failed to support the efficacy of GeneSight's ADHD and analgesic panels, and that, as of May 2019, the Company had removed those panels from the GeneSight test.

7. Los Angeles's investigation has revealed that Myriad knew it lacked scientific support for its ADHD and analgesic panels since before the start of the Class Period. It was the consensus among Myriad's scientific staff that Myriad lacked the data to support its claims that GeneSight could accurately match patients to pain and ADHD medications based on their genetic profiles. As multiple Myriad former employees described,[2] the support for the pain and ADHD tests was "unsubstantiated" and "conjecture." Myriad employees also raised such lack of supporting data, and the need to perform studies to generate helpful data, to senior executives at

[1] "Psychotropic" denotes drugs that affect a person's mental state and includes treatment for depression or other mental conditions.

[2] Former Employees and consultants of Myriad ("FEs") are described below and identified in this Complaint by number (FE 1, FE 2, etc.). For ease of comprehension and readability, the Complaint uses the pronoun 'he' and possessive 'his' in connection with the Former Employees. However, this convention is not meant to identify the actual gender of any of the Former Employees.

Myriad (including Defendant Bryan Dechairo, Executive Vice President of Clinical Development during the Class Period). Dechairo refused to consider conducting the proposed studies because they posed the risk of a negative result harmful to Myriad's ability to market GeneSight.

8. Instead, Myriad marketed and sold GeneSight for ADHD and pain indications for years without scientific support, collecting millions in revenue, based only on conjecture. As one former Myriad employee said, the inclusion of the ADHD and pain panels in the GeneSight offering was driven by marketing instead of science. When Myriad quietly removed the ADHD and pain panels from the GeneSight offering in 2019, an internal script for Company sales representatives stated that if a doctor pushed back and wanted the ADHD and pain panels, the representative should ask, "Do you want to prescribe a test to a patient that has ***little to no data***?"[3]

9. Myriad's claims that GeneSight was "clinically proven to enhance medication selection" for their GeneSight panel for patients suffering from depression also suffered a critical blow when Myriad learned the results of its highly-anticipated GUIDED study near the start of the Class Period.

10. In GUIDED, Myriad had compared how patients reacted to treatment for depression with GeneSight-recommended medications versus the patients' treatment as usual without the use of GeneSight. In randomized, controlled clinical trials like GUIDED, the sponsor of the trial pre-specifies before the trial begins what outcome measure it will use to determine whether the trial was a success or failure. That is called the study's "primary endpoint" and the study sponsor cannot change it after the fact. In the GUIDED study, GeneSight treatment failed to achieve the study's pre-specified primary endpoint of improving patients' depression

[3] Emphasis is added unless otherwise noted.

symptoms versus treatment as usual ("symptom improvement"). GUIDED was a failed trial and the implications of its results were potentially catastrophic for GeneSight's commercial viability.

11. Faced with the negative GUIDED results, instead of admitting that GeneSight had failed, Defendants improperly mined the GUIDED study data for any conceivable silver linings. That search resulted in Myriad misrepresenting the non-statistically significant results from two cherry-picked secondary endpoints ("response" and "remission")[4] as the statistically significant "primary goal" of the trial, when they were neither primary endpoints nor statistically significant.

12. The more endpoints that a clinical trial explores, the greater the chances of observing a false positive result simply by random chance. Accordingly, standard scientific and clinical practice requires that the threshold for declaring a result statistically significant must be made more demanding as more endpoints are added – a process called "multiplicity adjustment." Myriad's GUIDED study rule book (or "protocol") required that Myriad perform such a multiplicity adjustment for its secondary endpoints.

13. Pursuant to that required adjustment, GeneSight's results for the response and remission secondary endpoints in GUIDED were ***not*** statistically significant, yet Defendants repeatedly claimed to investors that they were. FDA guidance also provides that a trial sponsor may not draw conclusions from secondary endpoints if the primary endpoint fails. But that was precisely what Myriad did with the GUIDED study results, while simultaneously – and falsely – claiming that Myriad had conducted GUIDED in conformity with FDA guidance.

[4] The GUIDED protocol defines "response" as a 50% decrease in HAM-D17 score at week 8 of the trial, and defines "remission" as a HAM-D17 score of 7 or less also at week 8 of the trial. Unlike symptom improvement, neither response take into account the patient's morbidity at the start of the trial. As discussed below, for this reason, among others, symptom improvement is selected as the primary endpoint in depression trials.

14. On November 7, 2017, Defendant Capone touted the results of the GUIDED study to the market and claimed to investors that the "primary goal" of the trial was not only symptom reduction (the actual primary endpoint), but also patients' response and remission (which was not true). Capone declared that "in the 2 most critical endpoints for physicians and payers, response and remission" (which Capone described as the "2 gold standard clinical outcomes"), Myriad had "achieved ***a high degree of statistical significance***." Capone declared victory in GUIDED based on the improperly cherry-picked and scientifically invalid secondary endpoints, and claimed that, "with GeneSight now having amassed an extensive dossier for treatment-resistant depressed patients, and ***having demonstrated success in [the GUIDED] prospective clinical study***, we continue to believe this product can materially transform our financial performance in the future."

15. Defendants persisted to falsely and misleadingly describe the results of the GUIDED study throughout the Class Period:

- on January 8, 2018, Capone told investors that, in GUIDED, "GeneSight showed highly statistically significant results in the endpoints that matter most";
- on February 6, 2018, Capone claimed that GUIDED's "top line data" demonstrated GeneSight's ability to improve "the gold standard clinical outcomes of remission and response"; and
- on May 8, 2018, Capone stressed that "the most important thing we were able to demonstrate is significant improvements in remission and response."

Response and remission were neither the pre-specified primary endpoint, nor were the GeneSight results for those secondary endpoints statistically significant.

16. Defendants also publicly touted scientifically invalid post-hoc analyses of the GUIDED data that resulted from Defendants' improper after-the-fact data mining of the GUIDED data, claiming that the analyses showed statistically significant results. However, such hindsight analyses of the GUIDED study's data materially misrepresented the Study's failure and none of

the supposedly favorable results from the post-hoc analyses were actually statistically significant or clinically meaningful.

17. According to FE 1, a scientist in Myriad's Medical Affairs department during the Class Period, the internal "consensus" among Myriad's scientists was that such post-hoc analyses were just a "fishing expedition," a "sham" and "arbitrary," as Myriad conducted them after GUIDED failed its primary endpoint.

18. Securities analysts became keenly focused on the GUIDED study results and the timing of when a medical journal might publish a peer-reviewed article describing them, because coverage in a respected journal would impact Myriad's ability to justify GeneSight's very high cost to payors. But Myriad hid from investors how, when it attempted to submit the GUIDED study publication to the prestigious *American Journal of Psychiatry* ("*AJP*") for publication, the journal privately rejected it twice because Myriad's draft relied on GUIDED's secondary endpoints, which were not statistically significant.

19. When analysts pressed Myriad on why publication in a respected medical journal was delayed, Capone claimed the delay was caused ***"solely"*** by a journal's request for Myriad to disclose "the proprietary GeneSight algorithm" that Myriad uses to generate the GeneSight test's results. Capone told investors that Myriad had rejected the journal's request for the algorithm and that Myriad itself voluntarily withdrew the GUIDED manuscript "***solely*** based upon the desire to protect our intellectual property." This hid from investors that the *AJP* had independently found the GUIDED study paper to be methodologically and scientifically unsound and rejected it.

20. Myriad's lack of scientific support for its GeneSight panels were partially revealed to the market through a series of corrective disclosures. At each turn, however, Myriad

aggressively silenced critics and misled even the most sophisticated market analysts about what Myriad's data showed.

21. On October 31, 2018, the FDA publicly issued a Safety Communication that "warn[ed] against the use of many genetic tests with unapproved claims to predict patient response to specific medications." The FDA's skepticism of claims by makers of pharmacogenomic tests that their products could predict how a patient will respond to specific drug therapy, caused serious investor concern about Myriad's own claims to doctors, patients and investors about its most important product. In response to this news, the price of Myriad stock fell by 12.5% on November 1, 2018.

22. In order to allay investor concerns, and reverse the stock decline, Defendants intensified their assurances to investors that GeneSight was different from other pharmacogenetic tests in that its efficacy was amply supported by rigorous testing conducted in accordance with "FDA's guidance on clinical trials for depression" and would therefore be insulated from agency scrutiny.

23. But Myriad faced growing scrutiny related to its ADHD and analgesic panels from payors. As a result, and hidden from investors, by May 2019, Myriad decided to remove from the GeneSight test the ADHD and analgesic panels because they lacked scientific support. The Company, however, did not disclose this until August 2019 because of the negative impact it would have on the Company.

24. Myriad also concealed from investors the heightened scrutiny the Company faced from the FDA over GeneSight. As Myriad ultimately admitted on August 13, 2019, "earlier in 2019, we provided the FDA with clinical evidence and other information to support our GeneSight

psychotropic test" and "more recently, the FDA requested changes to the GeneSight test offering, and we have been in ongoing discussions with the FDA regarding its request."

25. On August 1, 2019, before disclosing the removal of GeneSight's ADHD and pain relief panels to investors, Myriad pre-announced to the market that the largest insurance company in the United States, UnitedHealthcare, had decided to cover the GeneSight test. This announcement sent Myriad's stock price soaring 54%. On the same day as this positive announcement, CEO Capone and CFO Riggsbee sold more than $7 million of their personally-held Myriad stock in pre-planned sales at artificially inflated prices.

26. Less than two weeks later, on August 13, 2019, only after Capone and Riggsbee made their multi-million dollar insider sales, Myriad revealed that the Company had removed the ADHD and analgesic panels from the GeneSight test offering because the panels lacked adequate scientific support. Myriad further disclosed that their removal had caused a decrease in demand for GeneSight, and a 15% decline in GeneSight revenue. On the same call, Myriad disclosed the negative news that the FDA had requested changes to the GeneSight test offering and that the Company has "been in ongoing discussions with the FDA regarding its request."

27. That day, Myriad also filed an Annual Report on Form 10-K with the SEC (the "2019 10-K"), which disclosed that the FDA had questioned whether Myriad had established the validity of GeneSight's purported benefits. It also revealed that, since at least late 2018, the FDA had increasingly questioned the claims of marketed genetics tests, such as GeneSight. On this news, Myriad's stock price fell $19.05 per share, or ***42.76%***—nearly half of the Company's total stock value—to close at $25.50 per share on August 14, 2019.

28. Then, on Myriad's November 4, 2019 earnings call, the Company revealed for the first time it overstated revenue attributable to its hereditary cancer test by $18 million. Myriad's

hereditary cancer tests were one of the Company's most significant products and accounted for more than half of all of Myriad's revenue during the Class Period. On the November 4, 2019 earnings call, Myriad disclosed that, since the beginning of 2019, the Company had experienced a significant increase in the number of denied and partially unpaid claims for the Company's cancer test as the result of a mandatory change in billing codes. As a result of its overstatement of hereditary cancer revenue it would be forced to take an $11.2 million out-of-period adjustment, and to lower its revenue accrual model by 8% going forward.

29. In response to revelation of these facts, Myriad's stock again declined sharply, falling more than 40%, from a close of $35.10 on November 4, 2019 to a close of $20.93 on November 5, 2019.

30. Finally, on the last day of the Class Period, Myriad shocked investors by announcing that Capone – who had been with Myriad for 17 years – was suddenly leaving the Company. Myriad also disclosed that, contrary to its bullish statements touting the UnitedHealthcare coverage decision as a watershed moment for GeneSight, Myriad was experiencing serious challenges obtaining reimbursement from the payor for administering the GeneSight test and, as a result, there was almost no contribution to GeneSight sales from the coverage decision.

31. In response to this news, Myriad's stock fell by 28%, from $29.29 at the close of market on February 6, 2020 to close at $21.02 on February 7, on high trading volume. Shortly thereafter, Defendant Dechairo was demoted and removed as an Executive Officer of Myriad.

32. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Los Angeles and other Class members have suffered significant damages.

II. JURISDICTION AND VENUE

33. The claims asserted herein arise under and pursuant to Sections 10(b), 20(a) and 20A of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a) and 78t-1) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

34. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

35. Venue is proper in this judicial district pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Myriad is headquartered in this judicial district, Defendants conduct business in this judicial district, and a significant portion of Defendants' activities took place within this judicial district.

36. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiff

37. Court-appointed Lead Plaintiff Los Angeles Fire and Police Pensions is a public pension plan that administers the defined benefit retirement plan for all sworn employees of the City of Los Angeles, including its firefighters and police officers. Lead Plaintiff Los Angeles currently serves 13,500 active members and 13,000 retirees and beneficiaries and, as of January 2020 had more than $25 billion in assets under management. As set forth in its certifications previously filed with the Court, Los Angeles acquired Myriad common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

B. Defendants

38. Myriad is a Delaware corporation with its principal executive offices located in Salt Lake City, Utah. Myriad common stock trades on the Nasdaq Global Select Market ("NASDAQ"), under the ticker symbol "MYGN."

39. Defendant Mark C. Capone served as Myriad's President and CEO from June 2015 until the end of the Class Period on February 6, 2020, when he and the Board "mutually agreed" he should resign from Myriad effective immediately. Capone previously served as President of Myriad Genetic Laboratories from March 2010 to June 2015.

40. Defendant Bryan Riggsbee has served as Myriad's CFO since 2014.

41. Defendant Bryan M. Dechairo has served as Myriad's Executive Vice President of Clinical Development since August 2012. As of February 10, 2020, after the end of the Class Period, Dechairo was demoted and is no longer an Executive Officer of Myriad.

42. Defendants Capone, Riggsbee, and Dechairo are sometimes referred to herein as the "Individual Defendants."

IV. SUMMARY OF THE FRAUD

A. Myriad's GeneSight and Hereditary Cancer Tests Were the Company's Two Most Important Products During the Class Period

43. Myriad is a molecular diagnostic company that develops and markets genetic lab tests that screen for the presence of certain traits or diseases. Throughout the Class Period, Myriad's most significant products by far were a "pharmacogenomic" test called GeneSight and genetic tests for hereditary cancer, including ovarian and breast cancer.

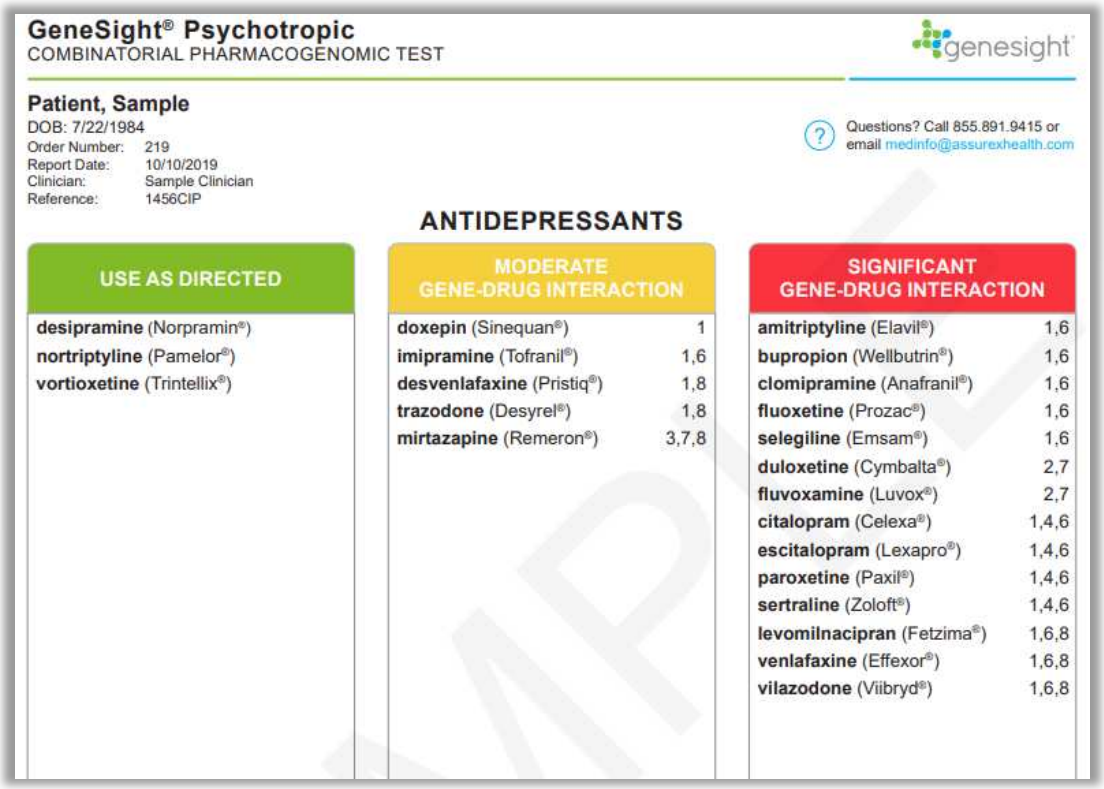
1. Myriad Hailed GeneSight as the Key to the Company's Growth and It Was the Focus of Investor Attention

44. Pharmacogenomic testing is a relatively new field that attempts to combine pharmacology (the study of the effects and modes of action of drugs) and genomics (the study of

genes and their functions). Pharmacogenomic tests are designed to detect the presence of genetic variations that affect the way a patient responds to drugs. Prior to, and throughout, the Class Period, Myriad claimed that its pharmacogenomic test, GeneSight, could inform prescribing decisions and significantly improve patient outcomes by providing doctors with information about how patients would metabolize, and thus respond to, specific drugs based on their genetic makeup, including most significantly: (1) psychotropic drugs used to treat major depressive disorder; (2) analgesic drugs used to treat pain; and (3) drugs used to treat attention-deficit-disorder, or "ADHD." The GeneSight test offered three different "panels," or sets of tests, for each of these three different drug classes.

45. Multi-gene testing that indicates the presence or absence of the same genetic variations screened by GeneSight was widely available during the Class Period for a fraction of the cost of Myriad's product. Myriad claimed, however, that unlike its cheaper competitors, GeneSight used a proprietary algorithm to make prescribing recommendations for specific drug therapies based on the patient's genetic makeup and presented those recommendations in a format that was easy for clinicians with little training in genetics to understand. Specifically, depending on the panels ordered, the GeneSight test would classify commonly prescribed drugs into three categories, as shown in Figure 1:

- "***Green***," which meant "Use As Directed. Likely well tolerated and efficacious";
- "***Yellow***," which meant "Moderate Gene-Drug Interaction. Dosing change may improve efficacy/tolerability"; and
- "***Red***," which meant "Significant Gene-Drug Interaction. Poorly tolerated and/or efficacy concerns."



GeneSight® Psychotropic
COMBINATORIAL PHARMACOGENOMIC TEST

genesight

Patient, Sample
DOB: 7/22/1984
Order Number: 219
Report Date: 10/10/2019
Clinician: Sample Clinician
Reference: 1456CIP

Questions? Call 855.891.9415 or email medinfo@assurexhealth.com

ANTIDEPRESSANTS

USE AS DIRECTED	MODERATE GENE-DRUG INTERACTION		SIGNIFICANT GENE-DRUG INTERACTION	
desipramine (Norpramin®)	**doxepin** (Sinequan®)	1	**amitriptyline** (Elavil®)	1,6
nortriptyline (Pamelor®)	**imipramine** (Tofranil®)	1,6	**bupropion** (Wellbutrin®)	1,6
vortioxetine (Trintellix®)	**desvenlafaxine** (Pristiq®)	1,8	**clomipramine** (Anafranil®)	1,6
	trazodone (Desyrel®)	1,8	**fluoxetine** (Prozac®)	1,6
	mirtazapine (Remeron®)	3,7,8	**selegiline** (Emsam®)	1,6
			duloxetine (Cymbalta®)	2,7
			fluvoxamine (Luvox®)	2,7
			citalopram (Celexa®)	1,4,6
			escitalopram (Lexapro®)	1,4,6
			paroxetine (Paxil®)	1,4,6
			sertraline (Zoloft®)	1,4,6
			levomilnacipran (Fetzima®)	1,6,8
			venlafaxine (Effexor®)	1,6,8
			vilazodone (Viibryd®)	1,6,8

Figure 1. Sample report for GeneSight's psychotropic panel. According to Myriad, the test uses a proprietary algorithm to make prescribing recommendations to doctors that divide commonly prescribed drugs into "green," "yellow," and "red" categories.

46. According to Myriad, GeneSight's supposed ability to recommend appropriate therapies and caution against inappropriate ones was the test's core value proposition and the Company's key justification for the high price charged for it.

47. GeneSight was first developed by Assurex Health, an Ohio-based company focused on genetic testing, which Myriad acquired in 2016. Defendants hailed GeneSight as a turning point for Myriad's business and the key to its future growth. In an August 3, 2016 press release, for instance, Defendant Capone trumpeted Myriad's acquisition, stating "Assurex provides Myriad access to GeneSight, one of the fastest growing new diagnostic tests ever in a multi-billion dollar global market and builds upon Myriad's commitment to expand into neuroscience, positioning us for long-term growth." In particular, Myriad touted GeneSight's

multi-billion dollar market potential in key indications of depression, ADHD, and pain relief (analgesia). For instance, in an August 3, 2016 investor presentation, Myriad trumpeted the success of GeneSight's psychotropic panel (marketed for use in making prescribing decisions to treat depression) as "one of the fastest growing new diagnostic tests in history," while also noting that the market for the test's ADHD and analgesic panels was ***three times*** the size of the market for the psychotropic panel and assuring investors the Company would invest in further penetrating these lucrative markets.

48. Following the Assurex acquisition, GeneSight quickly became Myriad's second-largest source of revenue (as discussed below, only the Company's hereditary cancer test generated more revenue). Indeed, on a February 7, 2017 investor call, Capone told investors that GeneSight's revenue was "rapidly approaching our current hereditary cancer revenue, showing the potential for this product to be transformative to our growth trajectory."

49. By the start of the Class Period, GeneSight had surpassed hereditary cancer to become Myriad's largest volume product, and, on its November 7, 2017 earnings call, the Company reported GeneSight had achieved "a new [revenue] record at $28.8 million" and had achieved explosive growth of "54% year-over-year on an adjusted basis and 12% sequentially." Indeed, Capone told investors on the Company's August 8, 2017 investor call that GeneSight "would represent revenue of $500 million per year" – almost equaling Myriad's Company-wide revenue for all of 2017 – "if fully reimbursed." As illustrated in Figure 2 below, GeneSight revenue grew rapidly during the Class Period, fueling Myriad's rising stock price.

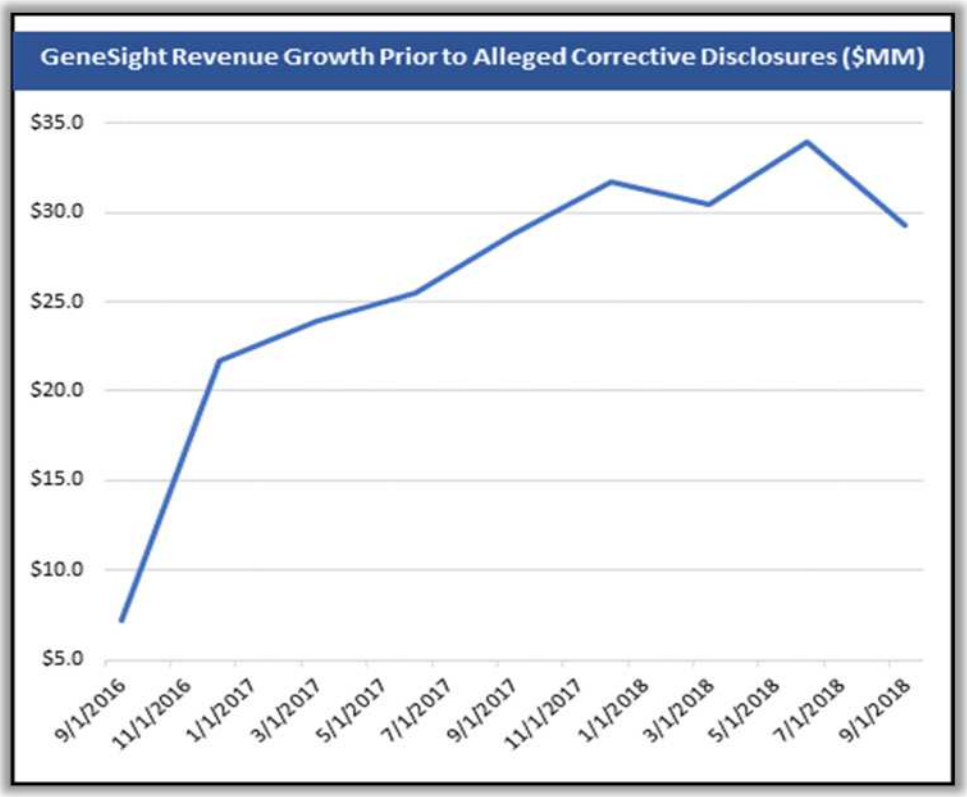


Figure 2. GeneSight revenue grew dramatically prior to, and during the Class Period, and analysts referred to the product as the Company's "most important growth driver."

50. Defendants continued to tout GeneSight's importance throughout the Class Period, discussing GeneSight on ***every*** investor call, frequently in response to repeated analyst questions on the subject. At a September 12, 2016 investor conference, for instance, Capone stated that GeneSight "arguably is one of the top three molecular diagnostic products in the industry," and "the market potential" for the test "is extensive. You are talking about a product that has over $10 billion of market potential for use with just the depression and the anxiety indications. And so, you have a very large market potential." Likewise, on Myriad's August 8, 2017 earnings call, Riggsbee stated, "With this product in the early stages of adoption and a largely untapped preventive care market, we see significant opportunity for continued GeneSight growth."

Likewise, And during a January 8, 2018 investor conference, Capone called GeneSight "one of [Myriad's] ***most important products***."

51. Analysts likewise recognized that the value of Myriad stock depended on GeneSight's commercial promise. For instance, in an August 9, 2017 report, Stephens analysts stated that GeneSight "continues to be the product we have the most conviction will be ***the driver in re-accelerated growth*** for" Myriad. Similarly, in a May 9, 2018 report, BTIG analysts called GeneSight "a ***major driver*** of [Myriad stock's] valuation." In a June 14, 2019 report, Barclays analysts characterized GeneSight as "Myriad's ***most important growth driver***" and stated in an August 14, 2019 report that "any risks which impair the growth trajectory of the test would limit valuation upside for the company."

2. Myriad's Hereditary Cancer Test Was the Company's Largest Revenue Producer, and Investors Counted on It to Sustain the Company as GeneSight Grew

52. Myriad offered hereditary cancer testing products that screened for genetic mutations associated with elevated risk for eight hereditary cancers, including breast and ovarian cancer. Myriad's hereditary cancer test was Myriad's first product, commercialized in the mid-1990s, and a core pillar in the Company's business. Indeed, as illustrated in Figure 3, below, Myriad's hereditary cancer testing accounted for more than half of all Myriad's revenue – and was by far the largest source of revenue for the Company – throughout the Class Period.

53. Prior to the start of the Class Period, Myriad had tried assiduously to keep competitors out of the marketplace for cancer screening. These efforts included Myriad's controversial bid to patent parts of the human genome, which the Supreme Court unanimously rejected. *See Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

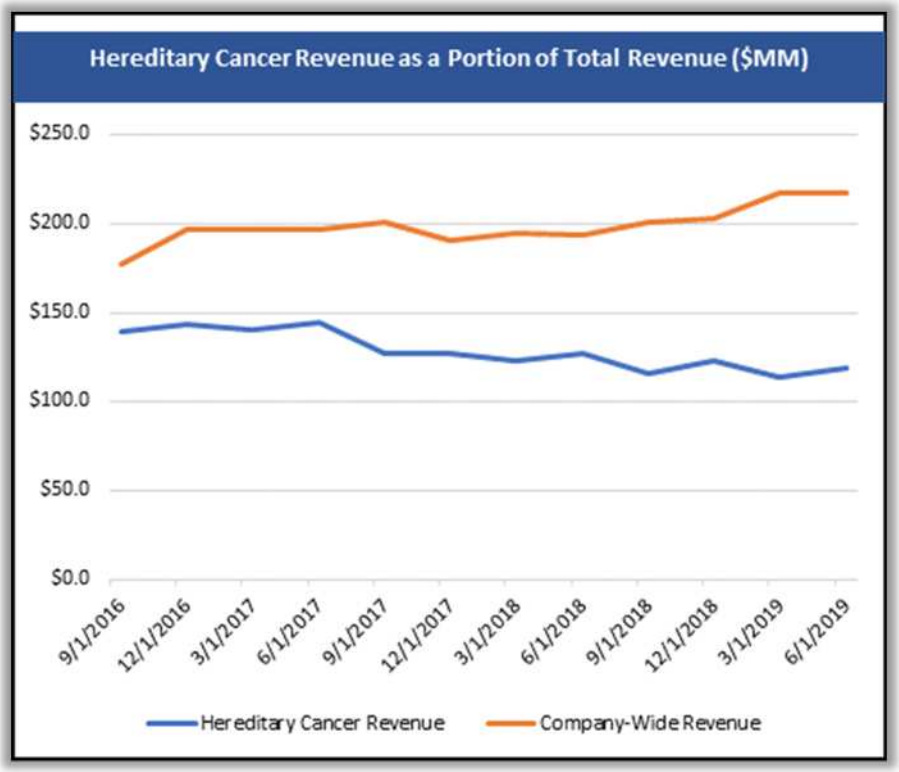


Figure 3. Myriad's hereditary cancer tests contributed more than half the Company's overall revenue during the Class Period and was a pillar of the Company's profitability. Maintaining this revenue stream was highly important to investors.

54. Despite Myriad's best attempts to exclude them, numerous competitors entered the market for hereditary cancer screening in the run up to, and throughout, the Class Period, putting negative pricing pressure on Myriad. It was critical to investors that Myriad maintain its hereditary cancer revenue in order to sustain Myriad as it worked to grow and expand its product offerings, particularly GeneSight. Indeed, investors viewed GeneSight's growth and the maintenance of Myriad's hereditary cancer revenue as the two single most important issues facing Myriad during the Class Period and the keys to the Company's profitability. As Morgan Stanley analysts stated in a February 7, 2018 report, "The narrative around [Myriad] includes optimism

around the GeneSight reimbursement outlook . . . and price stabilization in hereditary cancer/myRisk[5] that could support strong double-digit EPS growth beyond FY18."

55. As discussed below, Defendants made materially false and misleading statements to investors concerning both of these critical issues. Importantly, unlike pharmaceutical drugs or medical devices, genetic laboratory tests, like those manufactured by Myriad, are not subject to a rigorous FDA approval process designed to ensure their efficacy and safety before they are introduced to the market. Accordingly, investors are especially dependent on the integrity of statements by test manufacturers, like Myriad, about the efficacy and safety of their products.

B. Myriad Misled Investors About the Evidence Supporting the Efficacy of GeneSight's ADHD and Analgesic Panels

56. Throughout the Class Period, Defendants assured investors that ample clinical and scientific evidence demonstrated GeneSight, including its ADHD and analgesic panels, was highly effective and improved clinical outcomes for patients whose doctors prescribed drugs recommended by the test. For example, in Myriad's Forms 10-K issued throughout the Class Period, signed by Defendants Capone and Riggsbee and filed with the SEC, Myriad stated that GeneSight was "***clinically proven***" to "enhance medication selection" for "ADHD," "chronic pain," and "depression," among other conditions:

> In the neuroscience market, our GeneSight test meets a significant unmet clinical need and is the leading product for psychotropic drug selection. It is used by healthcare providers to help patients who are affected by neuropsychiatric conditions including depression, anxiety, ***ADHD***, bipolar disorder, schizophrenia, post-traumatic stress disorder (PTSD) and other behavioral health conditions, as well as ***chronic pain***. The test is ***clinically proven to enhance medication selection, helping healthcare providers get their patients on the right medication faster***.

[5]As Myriad's website explains, the Company's "myRisk" hereditary cancer test "is a 35-gene panel that identifies an elevated risk for eight hereditary cancers."

57. Defendants continued to specifically tout the efficacy of GeneSight's ADHD and analgesic panels throughout the Class Period. For instance, Myriad's website stated throughout the Class Period:

- "If you or your child have Attention-Deficit / Hyperactivity Disorder, this test can help quickly and ***accurately determine*** which drugs will work best with your (or your child's) genes";
- "The GeneSight ADHD genetic test can reduce [the anxiety of taking ADHD drugs] by helping doctors ***to identify and avoid ADHD medications more likely to cause side effects*** based on your genetics"; and
- "For those experiencing acute or chronic pain, this test analyzes how your genes affect your body's response to FDA-approved opioids, NSAIDs and muscle relaxants to ***accurately determine which medications are optimal***."

58. Defendants' statements touting GeneSight's efficacy, including the efficacy of the test's ADHD and chronic pain panels were materially misleading. In truth, as Defendants were well-aware, there was no meaningful evidence supporting GeneSight's claimed ability to predict patient response to particular ADHD or pain relief drugs. In other words, despite Defendants' repeated statements touting GeneSight's efficacy, they knew that there was no meaningful evidence that at least two of the test's three key drug therapy panels worked at all.

59. Indeed, as discussed further below, on August 13, 2019, Myriad belatedly admitted that the scientific evidence available to the Company failed to adequately support the efficacy of GeneSight's ADHD and pain relief panels, and that the Company had removed these panels from the GeneSight test offering because payors were refusing to reimburse claims for administering them for this same reason. Specifically, Defendant Riggsbee stated, "in May, we made the decision to discontinue our analgesic and ADHD products because . . . the level of clinical evidence did not meet the same high standard set by the GeneSight psychotropic test in the GUIDED study. In addition, ***a few payers expressed similar views***, and we wanted to eliminate any potential hurdles to commercial payer coverage for GeneSight psychotropic."

60. Myriad further disclosed that its withdrawal of the ADHD and analgesic panels had a significant negative impact on GeneSight revenue, and, indeed, reduced overall demand for GeneSight, including demand for the test's psychotropic panel. Myriad disclosed that in just the first month in which the panels were withdrawn, the reduced demand for GeneSight caused a 15% year-over-year decline in GeneSight revenue. By Myriad's first fiscal quarter 2020 (the three months ended September 30, 2019), Myriad had reported ***a 23% year-over-year decline*** in GeneSight revenue due to the withdrawal of the ADHD and analgesic panels because of their inadequate evidentiary support.

61. While, as set forth below, the market did not begin to learn the truth about GeneSight until the FDA issued a public warning about pharmacogenetic tests on October 31, 2018, Myriad's most senior executives, including Defendant Dechairo, had known for years – even prior to the start of the Class Period – that the data available to the Company failed to provide adequate evidence that the ADHD and analgesic panels were effective in predicting patient drug effects.

62. FE 2, a Medical Science Liaison at Assurex Health and then at Myriad until mid-2017 who helped develop the Company's communications about GeneSight, reported that, even prior to the start of the Class Period, it was well known within Myriad, including among Dechairo and other senior personnel, that the science did not support GeneSight's use of the ADHD and analgesic panels. Instead, according to FE 2, the data available to Myriad, which included non-public internal data collected from GeneSight patients, failed to demonstrate a clinically meaningful relationship between the genes tested as part of the ADHD and analgesic panels and patients' response to medications. These data, including analyses of Myriad's own internal data, showed that clinical considerations apart from the presence of these genes played a far more

significant role in drug response and, thus, the genes for which GeneSight screened were irrelevant for practical purposes in making prescribing decisions for ADHD and analgesic drug therapy. Even worse, FE 2 reported that as Myriad continued to accumulate data, including internal patient data, during his tenure at the Company, the empirical support for the ADHD and analgesic panels got even weaker.

63. The paucity of evidentiary support for the efficacy of the analgesic and ADHD panels was well-known and widely discussed inside Myriad. FE 2 stated that the overwhelming consensus in Myriad's Medical Affairs department – FE 2's department, which was responsible for providing scientific and clinical support for the Company's commercial products – was that the data did not support GeneSight's inclusion of the ADHD and analgesic panels. Indeed, FE 2 could not think of anyone he spoke to about this within Myriad that did not voice skepticism. Moreover, FE 2 reported that David Lewis, Myriad's Senior Manager of Bioinformatics and the senior Myriad scientist who ran the group responsible for analyzing GeneSight data, agreed that scientific support for the ADHD and analgesic panels was "weak." FE 2 reported that the inclusion of the ADHD and analgesic panels in GeneSight was driven more by marketing, and was pushed by the Company's marketing personnel, rather than by science.

64. FE 2 also stated that he, along with colleagues in Medical Affairs and other Company employees, raised the lack of evidentiary support for the ADHD and analgesic panels directly with Defendant Dechairo on numerous occasions prior to the start of the Class Period, including at routine Company offsite meetings. At these meetings, which occurred two to three times per year during FE 2's tenure, the Medical Affairs team provided feedback to Myriad executives and raised weaknesses and opportunities regarding the Company's products. FE 2 confirmed that Myriad scientists repeatedly raised the lack of evidentiary support for the ADHD

and analgesic panels with Dechairo at these meetings, including during an early 2017 meeting in Park City, Utah. At this meeting, FE 2 described to Dechairo analyses the Company should perform to obtain necessary clarity on the efficacy of GeneSight's panels, including ADHD and analgesic. To FE 2's astonishment, Dechairo declined to consider these proposals, stating that the risk of a negative result would harm Myriad's ability to market GeneSight. FE 2 felt that it was not a good sign for GeneSight if one of the Company's most senior executives was worried about what additional testing might show.

65. FE 1, a Medical Science Liaison at Myriad from May of 2018 to April of 2019 who, like FE 2, helped develop the Company's communications about GeneSight, also stated that the Company had "no data" supporting the efficacy of the ADHD and analgesic panels during the Class Period, and that Myriad's claim that it could match patients to specific ADHD and analgesic drugs based on the genes was "unsubstantiated" and "conjecture." FE 1 corroborated FE 2's report, stating that the overwhelming consensus among Myriad's scientific personnel during the Class Period was that there was not adequate empirical support for the efficacy of GeneSight's ADHD and analgesic panels, and that this serious issue was raised repeatedly with Myriad executives throughout his tenure. Indeed, at a Company off-site meeting in July 2018, FE 1 and other Medical Affairs personnel met with Myriad Neuroscience President Mark Verratti and "heated[ly]" repeated long-standing concerns that the Company needed to validate the effectiveness of the ADHD and analgesic panels before marketing the panels to doctors and patients. The Medical Affairs personnel were particularly adamant that Myriad validate GeneSight's ADHD panel because a large number of doctors ordered the ADHD panel and relied on its findings. FE 1 stated that Verratti acknowledged that ***Myriad had not validated*** GeneSight's ADHD and analgesic panels. According to FE 1, Verratti further responded that he

understood the Medical Affairs personnel did not want to be selling a product without support, but that Myriad was not inclined to perform the testing or analysis to provide that validation at that point in time.

66. FE 1 stated that Medical Affairs personnel continued to raise issues concerning the absence of empirical support for the ADHD and analgesic panels with Mike Jablonski, Vice President of Medical Affairs at Myriad Neuroscience. Jablonski told FE 1 and his colleagues that he continued to relate their concerns to Verratti, but that Verratti remained unwilling to commence any testing or analysis to validate the panels.

67. Notably, FE 1 confirmed that the ADHD panel in particular was a significant driver of demand for GeneSight, particularly as the Company expanded its marketing in 2018 to focus on pediatricians and pediatric psychiatrists. FE 1 reported that by late 2018, 30% to 40% of all GeneSight tests ordered were driven by demand for the ADHD panel.

68. FE 1 reported that he left the Company because he was uncomfortable touting these panels without any real empirical evidence. Rather than let the science lead, FE 1 stated that it was "all about what commercial wanted to do."

69. Indeed, in its own internal documents, Myriad stated that the effectiveness of the ADHD and analgesic panels was supported by "***little to no data***," corroborating reports by the Former Employees above. Specifically, an internal Myriad "Test Offering Change Talk Track" dated June 5, 2019, was a script for Myriad sales consultants to use with doctors, in order to explain to them Myriad's rationale for removing the ADHD and Analgesic panels from the GeneSight offering. If, after a sales representative informed the doctor of the decision to remove the ADHD and Analgesic panels, the doctor still continued to press the sales representative for

the Company's rationale, Myriad's Talk Track instructed the representative to push back on the doctor and ask him or her, "Do you want to prescribe a test to a patient that has ***little to no data***?"

70. Moreover, a June 18, 2019 post on CaféPharma.com, a message board frequented by insiders in the pharmaceutical and biotech industries, states that Myriad ultimately withdrew the ADHD and analgesic panels from GeneSight only after the FDA began scrutinizing the test in order to avoid receiving a Warning Letter from the agency admonishing the Company for misleadingly promoting the test. The CaféPharma post stated: "Myriad was in process of receiving a warning letter from FDA similar to the one received by Inova in April. Someone from FDA let executives know this was imminent. To avoid that, the ADHD and Analgesic panels were pulled immediately."

71. Notably, this message was posted months before Myriad publicly revealed the FDA had expressed concerns about GeneSight and that the Company had pulled its ADHD and analgesic panels, making clear it was authored by a Myriad employee with personal knowledge of these facts.

72. Importantly, the CaféPharma post concerning FDA scrutiny of GeneSight would not have given ordinary investors who happened to see the post any reason to investigate further; the single post was anonymous, which, absent confirmation of its accuracy by the Company or other independent, reliable third-party sources, called into question its validity. The post did not have sufficient indicia of reliability to be material to reasonable investors at the time of its posting. That changed, however, when Myriad disclosed on August 13, 2019 that the FDA was seriously questioning GeneSight's efficacy and that Myriad had withdrawn the test's ADHD and analgesic panels, confirming the claims made on CaféPharma approximately two months earlier. Myriad's August 2019 disclosures, when compared to the earlier CaféPharma post, now

creates the strong inference that the FDA's expressions of concern about GeneSight were known within Myriad well before they were publicly disclosed.

C. Myriad Misled Investors About the Evidence Supporting the Efficacy of GeneSight's Psychotropic Panel

73. Defendants also misled investors about the clinical trial data that supposedly demonstrated the efficacy of GeneSight's psychotropic panel. Throughout the Class Period, Defendants touted the efficacy of GeneSight's psychotropic panel, and, in particular, repeatedly told investors that the results of a "landmark" clinical trial of GeneSight's psychotropic panel called the "GUIDED study" proved the test significantly improved clinical outcomes for depression patients whose doctors prescribed psychotropic drugs recommended by the test.

74. As Myriad management repeatedly stated, and as Myriad investors recognized, the GUIDED study was the single most important step for Myriad in achieving widespread adoption and comprehensive reimbursement for GeneSight's psychotropic panel during the Class Period. While FDA approval, which requires proof of safety and efficacy through rigorous clinical testing, is not required to market lab tests, Myriad recognized that performing a large, randomized, blinded clinical study like GUIDED – the gold standard for proving drug or device efficacy – was essential to achieving robust payor reimbursement and widespread clinical adoption of GeneSight. Prior to GUIDED, the only studies of GeneSight had been small studies of dubious design and clinical import. GUIDED was to be the first real test of GeneSight's clinical value.

75. Indeed, Defendant Capone told investors that GUIDED was "the ***most important milestone*** for reimbursement . . . for GeneSight." Likewise, prior to the release of the GUIDED results, Capone told investors that the GUIDED "data will be instrumental in driving expanded coverage for GeneSight," and that "with a positive readout from the study that we think we are very well positioned with clinical validity," and that "given the size of the prospective study,

[GUIDED] is going to greatly facilitate obtaining private pay reimbursement." Similarly, Dechairo told investors that GUIDED "will provide a significant catalyst to broaden payer coverage" of GeneSight and that "the study will be instrumental in expanding medical professional society guideline and deepen the adoption from physicians."

76. Significantly, as discussed below, after the FDA issued its October 2018 public Safety Communication urging caution about the use of pharmacogenomic testing in prescribing psychotropic medication, Defendants repeatedly highlighted the GUIDED trial's supposedly "positive results" to assuage market concern and differentiate GeneSight from competing tests targeted by the FDA. Citing the GUIDED study, Defendants told investors that GeneSight offered the ***only*** pharmacogenomic test for psychotropic drug treatment whose efficacy was demonstrated by a "randomized controlled trial." Randomized controlled trials, in which patients are randomly assigned to comparator arms and blinded to treatment assignment, are the "gold standard" in clinical testing. Accordingly, Defendants' statements reassured investors that GeneSight would be insulated from FDA scrutiny. Unfortunately for investors, however, Defendants' statements were materially false and misleading.

1. Myriad's Critical Clinical Trial of GeneSight, the GUIDED study, Was a Failure

77. Myriad described the GUIDED study as a "double-blind, multi-center, randomized controlled trial assessing the impact of the GeneSight Psychotropic test (GeneSight) on psychiatric treatment response in 1,200 patients with major depressive disorder (MDD)." According to Myriad, the GUIDED study was "the largest ever pharmacogenomics depression trial," and "one of the largest prospective studies for molecular diagnostics."

78. Patients in the GUIDED trial were randomly assigned to one of two study "arms": (1) a "guided therapy" arm or (2) a "treatment as usual" arm. Physicians for patients assigned to

the "guided therapy arm" were provided with the results of their patients' GeneSight tests at the start of the study in order to inform prescribing decisions (though the physicians were not required to follow the test's recommendations). Physicians for patients in the "treatment as usual" ("TAU") arm were not to be provided with GeneSight test results for the first 12 weeks of the study.

79. Clinical drug trial standards mandate that before a trial begins, the drug or device manufacturer must prepare a "clinical trial protocol" that prespecifies the manner in which the clinical trial will be conducted, how the trial data will be analyzed, and, most importantly, how success will be defined and measured – *i.e.*, the study's "primary endpoint." As one noted treatise explains, "The study protocol can be viewed as a written agreement between the investigator [the drug or device company], the participant, and the scientific community." Friedman, et al., *Fundamentals of Clinical Trials*, at 12-14 (4th ed. 2010). The terms of the prespecified clinical trial protocol are regarded as sacrosanct because prespecification ensures that a trial sponsor like Myriad cannot skew the study results in its favor by changing the study's goals or parameters (or by engaging in other post-hoc manipulation) after the company has already seen the data.

80. The GUIDED study protocol provided that the study's primary endpoint was "symptom improvement," defined as a change in the patient's score on the Hamilton Depression Scale 17 ("HAM-D17"), a commonly used scale involving 17 different factors to measure depression symptoms, after 8 weeks. Thus, according to the GUIDED protocol, the trial would demonstrate GeneSight's efficacy, and could be declared a success, if patients assigned to the "guided therapy" arm showed statistically significantly greater "symptom improvement" than patients assigned to the "treatment as usual" arm. In accordance with widely-accepted scientific standards, a difference in symptom improvement would be declared "statistically significant" if

the "p-value"[6] associated with that difference was 0.05 or less. In other words, if the difference in symptom improvement observed in the trial was so large that there was a 5% (or lower) chance it would be observed by random chance alone.

81. The GUIDED clinical trial protocol also prespecified 65 so-called "secondary endpoints." Secondary endpoints measure outcomes that might help further characterize or support a clinical effect established by achievement of the primary endpoint. Positive results on secondary outcomes cannot independently support claims of a drug's or device's efficacy. As FDA guidance makes clear, "Positive results on the secondary endpoints can be interpreted ***only*** if there is first a demonstration of a treatment effect on the primary endpoint family."

82. Importantly, FDA guidance further explains, "It is recommended that the list of secondary endpoints be short, because the chance of demonstrating an effect on any secondary endpoint after appropriate correction for multiplicity becomes increasingly small as the number of endpoints increases." Stated differently, and as discussed in further detail below, the more secondary endpoints that a sponsor explores in a clinical trial, the greater the chance it will observe a false positive result just by random chance.

83. The GUIDED trial's results were a disaster for Myriad. GeneSight failed to achieve the primary endpoint of the GUIDED study: there was ***no statistically significant difference*** in symptom improvement between the GeneSight arm and the "treatment as usual" arm. In other words, from a statistical standpoint, those patients whose doctors made prescribing decisions with input from GeneSight fared no better in terms of symptom improvement than

[6] The p-value associated with a result represents the probability of observing that result by random chance alone. In standard scientific practice a p-value of 0.05 or lower – *i.e.*, a 5% (or lower) probability of observing the result by random chance – is considered "statistically significant." In clinical drug or device trials, a result must be statistically significant in order to attribute the observed effect to the drug or device being tested.

patients who never received GeneSight screening. The trial thus failed to show any clinical benefit associated with GeneSight.

84. Faced with that harsh reality, and the financial threat that the results posed to Myriad, Defendants went on a fishing expedition. Myriad improperly mined through the GUIDED trial's ***65*** secondary endpoints to find some ostensibly favorable evidence to report. Even worse, Myriad conducted numerous post-hoc analyses – never prespecified in Myriad's clinical trial rulebook – looking for some way to slice the data favorably for GeneSight.

2. Defendants Issued Numerous False and Misleading Statements About the GUIDED Trial and Its Results

85. On November 2, 2017, Myriad purported to announce the results of the GUIDED trial. But rather than acknowledge that the trial had failed to show any clinical benefit associated with GeneSight because the trial had missed its primary endpoint, Myriad improperly seized on ***two*** of the trial's 65 secondary endpoints – "remission rate" and "response rate" after 8 weeks[7] – to declare the GUIDED trial a success for GeneSight that strongly supported the product's efficacy.

86. Indeed, the Company's November 2, 2017 press release purported to announce the supposedly "positive results" of the GUIDED study, stating:

> The study was designed to evaluate three key endpoints relative to HAMD-17 scores: remission (HAMD-17 score ≤7), response (HAMD-17 reduction >50%), and symptom reduction.
>
> Patients receiving the GeneSight test achieved a ***clinically meaningful and statistically significant improvement*** in both remission rates ($p<0.01$) and response rates ($p=0.01$) at eight weeks compared to the treatment-as-usual group. In addition, patients who received the GeneSight test had a greater reduction in HAMD-17 scores after eight weeks, compared to the treatment-as-usual group, with the difference approaching statistical significance ($p=0.1$). Lastly, the

[7] The GUIDED protocol defines "response" as a 50% decrease in HAM-D17 score at week 8 of the trial, and defines "remission" as a HAM-D17 score of 7 or less also at week 8 of the trial.

> improvement in remission, response, and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period.

87. Myriad's press release was materially false and misleading. Contrary to Defendants' claims, GUIDED was ***not*** "designed to evaluate three key endpoints." Rather, GUIDED had a single primary endpoint, "symptom reduction," which GeneSight failed to achieve. Moreover, because GeneSight had failed to achieve this primary endpoint, the trial was ***not*** "positive," as Defendants claimed, but, rather, wholly failed to provide empirical evidence that GeneSight provided any clinical benefit. Rather than admit these materially negative facts, Defendants instead led the press release with the improperly cherry-picked "response" and "remission" results, which far from being "key endpoints," were only two of the study's 65 ***secondary*** endpoints. Indeed, on a November 7, 2017 earnings call with investors held just a few days later, Capone astonishingly characterized remission and response at 8 weeks as components of GUIDED's "***primary endpoint***."

88. Contrary to Defendants' statements that GeneSight patients in the study achieved "clinically meaningful and statistically significant improvement" in response and remission, FDA guidance and standard clinical trial practice make clear that these secondary endpoints could not even be analyzed because, as discussed above, there was no "demonstration of a treatment effect on the primary endpoint family." Thus, in reality, the "response" and "remission" results that Defendants enthusiastically touted provided no empirically sound support for GeneSight's efficacy.

89. Moreover, Defendants' claim that GeneSight patients in the GUIDED trial achieved "statistically significant improvement" in response and remission was false for additional reasons. In truth, when these results are analyzed in accordance with Myriad's own prespecified rules for the GUIDED trial, there is ***no statistically significant difference*** in response

and remission rates between GeneSight and "treatment as usual" patients. As discussed above, the more endpoints that a clinical trial explores, the greater the chances of observing a false positive result simply by random chance. Accordingly, standard scientific and clinical practice, as well as FDA guidance, requires that the threshold for declaring a result statistically significant must be made more demanding as more endpoints are added – a process called "multiplicity adjustment."

90. The GUIDED clinical trial protocol pre-specified that "[t]o account for multiple testing," Myriad was required to apply "the Sidak correction" to adjust the threshold for statistical significance.[8] With 65 secondary endpoints specified in the GUIDED protocol, the Sidak Correction shrinks the required significance level, or p-value, for each endpoint from 0.05 to 0.0008. In other words, to be statistically significant, GeneSight was required to achieve an effect size on its secondary endpoints so large that there would be only a 0.08% chance of observing that effect by chance. While Myriad's press release claimed that GeneSight patients achieved "statistically significant[ly]" greater remission and response than non-GeneSight patients, ***neither of these results met the threshold for significance set by Myriad's own clinical trial protocol***. For the remission endpoint, GeneSight's p-value was 0.013; for the response endpoint, GeneSight's p-value was 0.007 – both profoundly failing to meet the 0.0008 threshold required to declare statistical significance.

91. Notably, the GUIDED protocol lists Defendant Dechairo as the trial's "Sponsor Clinical Monitor," making clear that he was aware of its requirements.

[8] Specifically, the protocol states, "To account for multiple testing, the Sidak correction will be employed using the formula $1 – (1-\alpha)1/n$ where n is the number of independent tests and α is the nominal level (i.e., .05) of statistical significance."

92. Myriad's November 2, 2017 press release continued to misleadingly tout Myriad's clinically meaningless remission and response results to investors, telling them that doctors and payors would find these results highly compelling evidence of GeneSight's efficacy.

93. For instance, the press release quoted John Greden, the study's paid author, as stating, "From a clinician's perspective, better but not well is not good enough and significant improvements in response and remission are always the most-desired endpoints." Likewise, Dechairo stated in the press release, "Improving remission and response rates are key treatment goals of clinicians because they directly improve patients' lives and reduce healthcare costs. These endpoints also align with payer goals, and we look forward to having those discussions in the coming months."

94. In truth, however, as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial. Instead, to the extent these endpoints are prespecified in the first instance, they are set only as secondary endpoints, clearly indicating that clinicians do ***not*** view them as independent evidence of clinical effect, but merely tools to define the parameters of an already established effect. Thus, not only were the results Defendants touted neither "clinically meaningful" nor "statistically significant," but the endpoints *themselves* lacked the clinical value Defendants misleadingly ascribed to them, as Myriad scientists internally recognized.

95. Investors and market analysts were misled by Defendants' assertions about the GUIDED study results and believed that GeneSight's response and remission results were clinically meaningful, statistically significant, and constituted compelling evidence of GeneSight's efficacy, notwithstanding the study's failure to meet its primary endpoints. For example, on November 2, 2017:

- William Blair analysts rated Myriad stock "Outperform" and parroted Defendants' statements touting GeneSight's "highly statistically significant improvement" in response and remission in GUIDED and that these "data continue[] to support potential for payer coverage in the test."

- Likewise, Stephens analysts mischaracterized "response and remission" as among GUIDED's "three primary endpoints." Moreover, the analysts repeated Defendants' statements that GeneSight's response and remission results provided strong evidence of the product's efficacy: "We believe response and remission are the most important endpoints / outcomes for depression treatments, because this means the patient is actually getting 'well.' GeneSight met these endpoints." Significantly, Stephens analyst stated that some investors who were concerned about GeneSight's failure to achieve the primary endpoint were "confus[ed]."

- Similarly, Piper Jaffray analysts called GeneSight "the brightest of Myriad's growth assets" also repeating Defendants' misstatements that "Myriad hit two critical secondary endpoints" and that the GUIDED results "confirm[ed] there is still benefit to using GeneSight vs. treatment-as-usual." These analysts also reported their conversation with Myriad "management" following release of the results, which "suggests the second[ary] endpoints are still critical."

96. Throughout the Class Period, Defendants continued to hail the "unprecedented" and "landmark" GUIDED study as strongly demonstrating GeneSight's clinical efficacy, emphasizing the test's supposed "achiev[ment of] statistical significance for the ***2 gold standard*** clinical outcomes of response and remission," and falsely claiming that the study was designed and analyzed consistent with FDA guidance. For example:

- On a November 7, 2017 Myriad earnings call, Capone stated that response and remission were part of the GUIDED study's "primary goal"; that the GUIDED study data "clearly demonstrates the clinical utility of the GeneSight test," and Myriad achieved a "high degree of statistical significance" on the "2 gold standard clinical outcomes" of response and remission;

- At a January 8, 2018 investor conference, Capone stated that the GUIDED study "showed highly statistically significant results in the endpoints that matter most"—supposedly response and remission; and

- On the Company's February 6, 2018 earnings call, Capone told investors that the GUIDED "top line data" demonstrated "statistically significant improvements in the gold standard clinical outcomes of remission and response."

97. These statements, and others like them described in detail below, misstated that the trial's results on the response and remission endpoints were clinically meaningful and statistically significant, when as discussed above, both Myriad's own prespecified clinical trial protocol and the FDA guidance the Company claimed it complied with undermined those claims. Analysts relied on and accepted Defendants' materially misleading assertions. For example:

- In a November 9, 2017 report, Stephens analysts reiterated their Overweight rating of Myriad stock, stating "MYGN highlighted that response and remission were the most important endpoints. We tend to agree that response and remission will be the focus of payers and self-insured employers." These analysts repeated Defendants' statements dismissing concerns about GeneSight's failure to achieve the primary endpoint in GUIDED as "initial confusion" about the study results and concluded "Bottom line-we are still believers that we will see incremental GeneSight coverage."

- In a February 6, 2018 analyst report, Piper Jaffray analysts stated "We believe the key factor that could drive Myriad's stock higher is private payer coverage for its non-hereditary cancer tests (specifically GeneSight). We believe value-add tests will be eventually reimbursed."

- In a February 7, 2018 analyst report, Stephens analysts rated Myriad Overweight, stating, "GeneSight continues to outperform our expectations . . . . Mgmt called out that 30% of psychs domestically (or 12,500) ordered GeneSight in the period. We believe this lends some credence to mgmt's discussion that response and remission are what physicians are tuned into from the prospective study, the top line results of which were released in October."

3. To Avoid Exposing their Claims About GUIDED to Scientific Scrutiny, Defendants Presented the Study Results at an "Invitation Only" Symposium

98. When Myriad initially released the "top-line results" of the GUIDED study in November 2017, it stated that it intended to present the full results at the American Psychiatric Association's ("APA") annual conference on May 8, 2018 in New York City. Professional medical conferences are important events for both doctors and investors because they serve as a forum in which pharmaceutical and biotechnology companies present comprehensive reports of their latest clinical trial results to a sophisticated audience of fellow scientists and clinicians.

99. Indeed, following Myriad's November 2017 announcement, analysts repeatedly noted that the market was keenly awaiting the presentation of the full GUIDED study data at the May 2018 APA conference. For instance, in a November 9, 2017 report, Stephens analysts stated, "We'd look for more clarity around Genesight data next May at APA, but remain confident in the market potential for that test." Likewise, in a March 28, 2018 report, Morgan Stanley analysts wrote, "The presentation and publication of full data from the GeneSight pivotal study data in May/June should address questions on why the study failed its primary endpoint but ***succeeded on secondary endpoints***, and may delve into patient subgroups."

100. In order to avoid the scrutiny of the scientific community, however, Myriad chose not to secure a formal slot at the 2018 APA conference. Instead, Myriad took the highly unusual step of hosting an off-site, invitation-only "satellite symposium" with a carefully curated audience of friendly investment bankers, securities analysts, and doctors. Notably, Myriad still claimed to have "presented" the GUIDED study at the APA conference, though this was only a "poster presentation" where Myriad's paid outside author, John Greden, simply talked to people that happened to stop by Myriad's table outside the conference.

101. Beginning with Myriad's off-site presentation of the GUIDED study's supposed results, and thereafter throughout the Class Period, Defendants touted the results of a handful of improper "post-hoc analyses," *i.e.*, analyses that were never even mentioned in GUIDED's prespecified clinical trial protocol, as further strong evidence that GeneSight's psychotropic panel greatly improved clinical outcomes for patients who used the test. These improper post-hoc analyses were all performed ***after*** Myriad had combed through the trial data and ascertained which analyses would appear to present positively for GeneSight. The analyses were nothing more than

the product of Myriad's desperate attempts to manufacture positive results from the GUIDED data and declare "endpoints" by hindsight.

102. Specifically, at its May 2018 off-site meeting, Myriad presented the supposed results of an analysis isolating the small subgroup of GUIDED patients who entered the study on "incongruent" medications that GeneSight predicted would have negative gene-drug interactions (in other words, medications with "red" results on the GeneSight test). Defendants claimed that patients in this "red" medication subgroup who switched to medications GeneSight predicted would have moderate or no negative gene-drug interactions (in other words, medications with "yellow" or "green" results in the GeneSight test) "***performed significantly better***" than those who remained on "red" medications. In particular, Defendant Dechairo claimed that patients who switched from "red" medications performed better than patients who stayed on "red" medication in terms of symptom improvement, GUIDED's primary endpoint, and both the remission and response secondary endpoints, stating:

> Remission rates among these patients were 153% higher, response rates were 71% higher, and symptoms were improved by 59%, and ***all of these results were statistically significant. In our view, these impressive data established a clear new standard of care***.[9]

103. Subsequently, by January 2019, Defendants began to misleadingly tout the results of yet another improper post-hoc analysis of the GUIDED data. Defendants claimed that if all the patients who entered the study on "green" medication – *i.e.* medication that GeneSight predicted would cause no negative gene-drug interaction – were excluded from the trial, GeneSight would achieve its primary endpoint in the GUIDED trial. Specifically, Defendants

[9] The p-values reported for these results were: remission ($p = 0.0067$); response ($p = 0.0364$); and symptom improvement ($p = 0.0018$), all missing by a wide margin the threshold required to declare statistical significance, which, as discussed below, further shrank to (at least) 0.00074 to account for Myriad's two additional improper analyses beyond the 65 secondary endpoints prespecified in the GUIDED protocol.

claimed that, once "green" patients were excluded, GeneSight patients showed statistically significantly greater "symptom improvement" at week 8 than patients in the "treatment as usual" arm, with a p-value of 0.029. Likewise, Defendants claimed that – again, taking out all "green" patients – GeneSight patients showed statistically significantly greater "response" and "remission" at week 8 than patients in the "treatment as usual" arm, with a p-value of 0.008 and 0.003, respectively.

104. Analysts were highly encouraged by Defendants' statements touting Myriad's post-hoc analyses. For instance, in the days following Myriad's May 8, 2018 off-site presentation:

- William Blair wrote that "Myriad presented what we characterize as ***compelling subset data*** at the APA meeting" and "[a]t the Symposium Monday evening, Myriad provided additional data around the subset analysis"—i.e., that "the patient population previously receiving Incongruent medication experienced the most symptom improvement with GeneSight guided therapy."

- Stephens reported that "we believe the most compelling data is that for those patients who, according to GeneSight, are taking an antidepressant that does fit their genetic profile, they see a 153% improvement in remission, a 71% improvement in response and a 59% improvement in symptom reduction when following the GeneSight guided treatment recommendation vs. the 'treat as usual' group."

- Deutsche Bank wrote that "the magnitude of improvement in the 21% of patients who entered the study on 'incongruent' medication (not a match to the patient's genetic profile as indicated by a red score on the GeneSight test) was ***striking*** and statistically significant across all categories."

105. Unfortunately for investors, Defendants' statements touting the results of Myriad's post-hoc analyses of the GUIDED data were false and misleading because, as with GUIDED's secondary endpoints, none of the supposedly favorable results were actually statistically significant or clinically meaningful. As discussed above, the FDA guidance Defendants purported to follow in conducting and reporting the GUIDED study results states that positive results on non-primary endpoints cannot be interpreted unless a positive result on the primary endpoint is achieved.

106. Moreover, as Myriad continued to improperly slice and dice the GUIDED data in a desperate search for ostensibly positive results, the Company's own pre-specified clinical trial protocol made clear that Myriad was required to make additional "multiplicity adjustments." As discussed above, these adjustments raise the bar for declaring a result "statistically significant." Even assuming Myriad only conducted two additional post-hoc analyses (though subsequent publications make clear it conducted far more), the Sidak Correction – the methodology Myriad said it would apply to account for multiple testing – shrinks the p-value required to achieve statistical significance to 0.00074. ***None*** of the results Defendants reported in their post-hoc analyses met this threshold, and thus none could be declared statistically significant.

107. Additionally, while Myriad touted the fact that GUIDED was a "randomized" controlled trial – the gold standard of clinical trials, providing the most empirically robust results – neither of these post-hoc analyses were actually protected by randomization. While patients were randomized to treatment arms (guided therapy versus treatment as usual), they were ***not*** randomly assigned to groups of "congruent and incongruent medicine-takers" or "medication switchers and non-switchers." Accordingly, even putting aside the fact that when calculated pursuant to the study protocol none of results of these post-hoc analyses are statistically significant, it was misleading for Defendants to claim that these results were clinically meaningful when, in truth, one cannot tell from these post-hoc analyses whether any claimed "effect" is due to switching from an "incongruent" medication to a "congruent" one or, instead, due to some other non-randomized variable that happens to be correlated to a patient's status as either "congruent" or "incongruent."

108. Contrary to Defendants' public statements to investors, Myriad internally recognized that the GUIDED study's disappointing results failed to provide much-needed support

for GeneSight's psychotropic panel. FE 1 reported that, as with GeneSight's ADHD and analgesic panels, the consensus among Myriad's scientific personnel was that GUIDED failed to provide meaningful clinical evidence supporting the efficacy of GeneSight's psychotropic panel. "When I realized that the majority of us didn't believe in the product, I knew it was time to get out of there."

109. FE 1 reported that Myriad's Medical Affairs scientists overwhelmingly agreed that the Company's attempt to hold up the results of post-hoc analyses and just two of the GUIDED study's numerous secondary endpoints as clinical evidence that the psychotropic panel was effective, notwithstanding the failure of the primary endpoint, was a "sham" and a "fishing expedition." As FE 1 explained, Myriad was "mining the data for whatever they could find that was significant."

110. Moreover, FE 1 stated that Myriad's Medical Affairs team also discussed and agreed that, contrary to the Defendants' claims, the secondary endpoints (*i.e.*, the response and remission results) and post-hoc analyses' results the Company touted were ***not*** statistically significant. FE 1 confirmed that the GUIDED protocol codified the requirement that the p-values for the results on the study's non-primary endpoints be adjusted for multiplicity and that, if the adjustment were made as required, ***none*** of the results were actually statistically significant.

111. FE 1 further stated that the consensus of the scientists inside Myriad was that it was further "misleading" for the Company to tout the remission and response data (*i.e.*, the two cherry-picked secondary endpoints) because, contrary to Defendants' statements, remission and response are not "gold standard" endpoints. Rather, as FE 1 confirmed, both endpoints have always been treated as secondary because, among other things, they do not take account of the starting point of the patient's morbidity. Rather, Myriad's scientists agreed that the true "gold

standard" endpoint was "symptom improvement" – the endpoint selected as primary in the GUIDED study and which GeneSight failed to achieve. Moreover, Myriad's Medical Affairs scientists agreed that the clinical significance of the results on GUIDED's response and remission data was "basically nothing" because the absolute size of the effect observed was very small.

112. FE 1 further explained that Myriad's post-hoc "congruent/incongruent" analysis (which focused on patients who entered the study on "red" medication and compared those who switched to "green") defined "congruence" in a way that was inconsistent with the statements the Company made when marketing the test to doctors. Specifically, in marketing the test, Myriad told doctors that if a patient's GeneSight results classify Prozac, for example, as a "red" medication, then either switching medication ***or*** reducing the patient's dosage are ***both*** "congruent" with the test's recommendations. However, Myriad's post-hoc analysis failed to classify patients whose dosage was adjusted as having switched to "congruent" medication, and classified them as remaining on "incongruent" medication instead. As a result, Myriad's post-hoc analysis fails to reflect actual clinical use of the test as directed by the Company. FE 1 stated that these post-hoc analyses were "arbitrary." Myriad "picked a set of criteria and that analysis worked out, so that's what they went with."

113. Relatedly, FE 1 reported that Myriad scientists were also skeptical of Myriad's public excuse for GeneSight's failure to meet GUIDED's primary endpoint. Myriad claimed that the patients in the GeneSight arm "shifted towards extreme improvement," while patients in the treatment as usual arm were shifted "towards modest improvement," washing out any difference on average. FE 1 was unaware of any statistical analysis Myriad had done to actually substantiate that the claimed "skew" was statistically meaningful, and, again, his scientific colleagues believed this claim was unsupported. Indeed, FE 1 reported that the Company's Medical Affairs requested

statistical data in order to vet this claim, however, those data were never provided to the scientific team.

114. The skepticism about GeneSight's psychotropic panel privately expressed by Myriad's scientific personnel was borne out by individual clinician feedback received by Company personnel. FE 1, stated that approximately 25% of the doctors he and his Medical Affairs colleagues spoke to reported that following GeneSight's recommendations affirmatively led to adverse clinical outcomes with their patients. FE 1 recalled a Westboro, Massachusetts doctor in particular who said that in almost every case in which he switched a patient's medication on GeneSight's recommendation, the clinical outcome was negative. FE 1 stated that numerous other doctors reported that GeneSight was not effective and that they did not see the value in the test because it was not really offering anything above and beyond clinical judgment.

115. Despite the internal skepticism about the efficacy of GeneSight's psychotropic panel, Defendants continued to claim to investors throughout the Class Period that the GUIDED study data, including Myriad's post-hoc analyses of it, supported Myriad's claims of efficacy. For example:

- On the Company's May 8, 2018 earnings call, Capone stated that the GUIDED study data "showed the ability of GeneSight to ***significantly improve outcomes in treatment-resistant depressed patients***."
- On that same May 8, 2018 call, Capone further stated that the GUIDED study showed "***a highly statistically significant improvement*** in remission and response rates," and Dechairo went on to state that "that proves the ***clinical validity*** of the test."
- At a June 12, 2018 Goldman Sachs investor conference, Capone stated that the GUIDED "***data was excellent***. It showed a 50% increase in remission and a 30% increase in response for patients whose care was guided by GeneSight."
- At the May 16, 2018 Bank of America Merrill Lynch investor conference, Capone stated, "at the 8-week time point, which is the standard FDA approval time point . . . [W]e saw dramatic differences between those 2, 153% improvement in remissions, 71% improvement in response and a 59% improvement in symptoms,

all of which were statistically significant. And so en masse, the data ***showed very clearly that treating patients with GeneSight would enable better outcomes*** than treatment-as-usual arm that was optimized by psychiatrists.

- At a September 13, 2018 Morgan Stanley investor conference, Capone stated, "I think one of the easy surrogate endpoints in this case is the number of patients that are on red medications. So ***that's really important data***, that hopefully all the investors have looked at for the GeneSight study, that shows what happens when you switch a patient off of red medications compared to those patients that stay on red medications. And ***the results were striking and highly statistically significant across all endpoints***."

116. Defendants made these statements knowing, or with severe recklessness, that Myriad's data did not support these claims.

4. The *American Journal of Psychiatry* Privately Rejected the GUIDED study Manuscript Twice Because of Its Failed Endpoint and Methodological Flaws

117. Critically, in the third quarter of 2018 (the three months ended March 31, 2018), Myriad executives also privately received clear warnings from top scientists and clinicians outside the Company that the GUIDED results failed to support Defendants' claims about GeneSight's efficacy when peer reviewers for a prominent medical journal, who reviewed the Company's submission and underlying data, ***twice rejected*** Myriad's request that it publish the GUIDED results. Specifically, in May 2018 Myriad submitted the GUIDED results for publication in the *American Journal of Psychiatry* ("*AJP*"), the official medical journal of the APA and a highly prominent journal in the field of psychiatry. Publicly, Myriad stated, including at a June 12, 2018 investor conference, that the Company continued to expect publication of the study results around June 30, noting it was "[a] near-term activity that we would expect to happen . . . in the coming weeks ahead."

118. Despite missing this deadline, Defendants continued to reassure investors that all was well with GUIDED's progress towards publication. On the Company's August 21, 2018 earnings call, for instance, Defendants told investors that they were "encouraged with . . . the

future publication," which was in the "latter stages of review." Defendants attributed the delay to the summer months and a large number of authors in the review process.

119. Unbeknownst to investors, in late summer 2018, the *AJP* privately informed Myriad that the journal could not, and would not, publish the Company's claims that GUIDED had provided evidence of GeneSight's efficacy. FE 1 reported that, among other things, the *AJP's* peer reviewers pointed out that GeneSight had failed to achieve the study's primary endpoint, and that Myriad's heavy reliance on the supposedly "statistically significant" results on two of the study's many secondary endpoints was misplaced, since those results had not been adjusted for multiplicity, and, once adjusted, were, in truth, ***not*** statistically significant at all.

120. FE 1 stated that Myriad submitted a private response to *AJP's* peer reviewers, citing the Company's post-hoc analyses discussed above, but, later in the summer of 2018, the *AJP* once again explained to Myriad that its claims lacked scientific validity and rejected the Company's GUIDED manuscript a second time.

121. Myriad, however, ignored these warnings, and continued to unequivocally tout GUIDED publicly as strong evidence of GeneSight's efficacy. Indeed, by August 20, 2018, Myriad had switched journals and sought publication in the *Journal of Psychiatric Research*, a far less prominent journal with an "impact factor" about one fourth the size of *AJP*'s.[10]

122. Significantly, Defendants hid from investors that *AJP* had rejected the GUIDED study manuscript. For instance, Capone's statement on the August 21, 2018 investor call described above that GUIDED was in the "latter stages of review" failed to disclose that *AJP* had declined to publish Myriad's manuscript because the Company's claims were unsound and that,

[10] "Impact factor" measures the yearly average number of citations a journal's recent articles receive. The measure is considered a proxy for the relative importance of a journal in a particular field.

far from being in the "latter stages of review," the study was only in its second day of review at the *Journal of Psychiatric Research* after its rejection from a far more prestigious journal.

123. Likewise, on Myriad's November 6, 2018 earnings call with investors, an analyst asked Defendants to explain why the GUIDED results were taking so long to publish. Defendant Capone falsely responded that Myriad had ***voluntarily withdrawn*** the GUIDED manuscript from an unnamed journal "***solely*** based upon the desire to protect our intellectual property" in response to the journal's request for a copy of the GeneSight algorithm. In truth, as discussed above, Myriad's submission to the *AJP* was ***rejected*** because the journal concluded that the Company's claims, including its claim that GeneSight's response and remission results were statistically significant, were not scientifically valid.

124. As discussed in further detail below, Defendants' false statements about the publication of the GUIDED results were highly material to investors. For instance, at a May 8, 2018 investor conference, Capone acknowledged that publication of the GUIDED results in a peer-reviewed medical journal "will be important because many payers need to have that reference for their coverage decision. They need to be able to cite a peer-reviewed journal article, and so that's going to be an important publication." Likewise, on Myriad's February 6, 2018 earnings call, an analyst asked when the Company would present the full GUIDED dataset in a scientific forum. Riggsbee repeated that "coverage decisions [about GeneSight] from payers" would not occur until "***after*** publication of the results in a peer-reviewed journal." Similarly, at a June 12, 2018 Goldman Sachs Global Healthcare investor conference, Capone stated that "the keys to getting reimbursement are the publication of [GUIDED]."

5. Defendants Increased Their False Claims to Investors After the FDA Publicly Warned Against the Use of "Many Genetic Tests" to Predict Patient Response to Specific Drugs

125. On October 31, 2018, the FDA issued a Safety Communication "warn[ing] against the use of many genetic tests with unapproved claims to predict patient response to specific medications." The FDA's apparent skepticism of claims by makers of pharmacogenomic tests, like GeneSight, that their products could predict how a patient will respond to specific drug therapy, caused investor concern about Myriad's most important product.

126. In order to allay these concerns, Defendants ramped up their false and misleading statements, and assured investors that the FDA was "well aware" that GeneSight was unique among competitors in that its efficacy was demonstrated by a randomized controlled clinical trial – *i.e.*, GUIDED – and thus Myriad's product was safe from adverse FDA action. For example:

- On Myriad's November 6, 2018 earnings call, Capone stated that the FDA was "well aware that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has ***clear clinical evidence demonstrating improved patient outcomes***. That difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing."

- On both Myriad's May 8, 2018 and January 4, 2019 earnings call, Capone stated that the "design and rigor of the [GUIDED] study [are] similar to studies conducted for a pharmaceutical seeking approval from the FDA."

- Myriad's GUIDED paper, published on January 4, 2019, stated that "the study design is in line with the recent FDA draft guidance for MDD trials."

- On Myriad's January 4, 2019 investor call, Capone specifically referenced a conversation he had with the FDA Director responsible for the division regulating medical devices on the same day the Safety Communication was issued, and stated "***we're in a very different space*** [from competing tests] . . . . So I know ***there is a very clear distinction in the line, and I think that distinction remains***."

- At a May 15, 2019 investor conference, Riggsbee stated, "when you look at the large study that we had in GUIDED, we have the data out there that really is what separates us and what will make the test quite frankly more durable over time."

- At a June 11, 2019 investor conference, Capone stated, Myriad was "the only company that has done a large prospect[ive] Phase III study" of its pharmacogenomic test, *i.e.* GUIDED, the results of which "demonstrated improved patient outcomes."

127. Moreover, Defendants continued to repeatedly tout the supposedly statistically significant results from the GUIDED study's secondary endpoints and placed heavy focus on the post-hoc analyses of the data. For instance, on the January 4, 2019 investor call, Dechairo claimed that Myriad's post-hoc analysis "clearly demonstrates that GeneSight improves outcomes for the 70% of patients taking medications that require modification based upon their genetic profile." Likewise, during a May 21, 2019 investor conference, Capone stated that in the Company's post-hoc analyses of the GUIDED data, Myriad saw "even better results, highly statistically significant results in every endpoint for the GeneSight treated arm."

128. As discussed above, Defendants statements were materially false and misleading. Contrary to Defendants' statements, the FDA was ***not*** "well aware" that GUIDED provided "clear clinical evidence" of GeneSight's efficacy. As discussed above, Myriad's analysis of the GUIDED study data violated not only FDA guidance, but the terms of Myriad's own GUIDED study protocol. Moreover, as discussed below, by no later than May of 2019, the FDA had privately expressed serious concerns about GeneSight to Myriad. Analysts, however, were greatly comforted by Defendants' prior misleading soothing statements:

- In a November 1, 2018 report, PiperJaffray analysts wrote that the "FDA argues many of the tests lack the appropriate clinical evidence to support drug selection. Myriad, to its credit, has been a leader in producing clinical results that support GeneSight (including the soon-to-be-published GUIDED study)."

- Stephens analysts issued a November 9 report stating, "the FDA issued a notice for pharmacogenomic testing cautioning providers/patients about using tests that are not backed up by clinically validated evidence . . . . Ultimately, ***MYGN wins*** if an environment evolves that requires more validations and stepped up regulatory oversight."

6. The FDA Privately Expressed Serious Concerns About GeneSight to Myriad, Including Requesting That Myriad Change Its Test Offering

129. Unbeknownst to investors, by no later than May 2019, the FDA privately told Myriad that it did not believe there was adequate evidence to support the Company's claims that GeneSight could predict patient response to specific medications and requested that GeneSight make changes to the test. As Myriad ultimately admitted in its August 13, 2019 earnings call, "earlier in 2019, we provided the FDA with clinical evidence and other information to support our GeneSight psychotropic test. More recently, the FDA requested changes to the GeneSight test offering, and we have been in ongoing discussions with the FDA regarding its request."

130. As discussed above, a June 18, 2019 post on CaféPharma.com, a message board frequented by insiders in the pharmaceutical and biotech industries, makes clear that the FDA had expressed concerns about GeneSight, and even threatened Myriad with a Warning Letter for misleadingly promoting the test, long before the Company publicly disclosed the agency's concerns in mid-August. Again, the Café Pharma post stated: "Myriad was in process of receiving a warning letter from FDA similar to the one received by Inova in April. Someone from FDA let executives know this was imminent. To avoid that, the ADHD and Analgesic panels were pulled immediately." As discussed above, Myriad discontinued GeneSight's ADHD and analgesic panels in May 2019. Thus, the post, consistent with the Company's discontinuation of those panels, demonstrates that the FDA's expressions of concern about GeneSight must have also occurred in May 2019.

131. As discussed above, the single anonymous CaféPharma post concerning FDA scrutiny of GeneSight would not have given ordinary investors who happened to see the post any reason to investigate further. That changed, however, when Myriad disclosed on August 13, 2019 that the FDA was seriously questioning GeneSight's efficacy, confirming the claims made on

CaféPharma approximately two months earlier. Myriad's August 2019 disclosures, when compared to the earlier CaféPharma post, now create the strong inference that the FDA's expressions of concern about GeneSight were known within Myriad well before they were publicly disclosed.

132. On September 18, 2019, the American Clinical Laboratory Association ("ACLA"), a lobbying group for the clinical laboratory industry whose board of directors counts Defendant Capone as a member, published a letter it had sent to the FDA the previous week. This letter elucidated the drastic changes to GeneSight the FDA had asked Myriad to make earlier in the year. ACLA's letter made clear that no later than July 2019, the FDA "demanded" that Myriad "stop offering PGx tests," *i.e.*, pharmacogenomic tests, that, like GeneSight, "reference specific drugs or drug classes unless approved by the FDA." In other words, Myriad would either have to remove all of GeneSight's references to specific drugs or seek FDA approval of the test.

133. By July 31, 2019, in a gambit to mollify the FDA, Myriad planned to remove 32 of GeneSight's 56 medications from the psychotropic panel because, as Myriad's move clearly acknowledged, the Company had inadequate evidence to support its claims that GeneSight could accurately predict patient response to those medications. Although Myriad did not execute on that grave internal decision—which would have decimated GeneSight's commercial viability—Myriad came so close that, on July 31, 2019, it internally formally announced the removal of those medications to its entire national sales force and subsequently informed sales representatives that the removal would occur on August 15, 2019.

134. As FE 3, a former Molecular Sales Consultant at Myriad Neuroscience from before the Class Period to November 2019 said, on July 31, 2019, Myriad held a nationwide call with its sales representatives to inform them that Myriad would be changing the psychotropic panel, such

that instead of reporting on 56 medications it would be reporting only on 24 medications (22 anti-depressants and 2 anti-psychotic medications), due to the FDA's safety bulletin on pharmacogenomic tests. FE 3 stated that while GeneSight's psychotropic panel included, for instance, mood stabilizers among the drugs analyzed, there was not much data to support the accuracy of those recommendations. The Company said that it needed to focus on what it could independently support. FE 3 reported that compared to competitor tests, this change would be tantamount to Myriad shutting its doors because many physicians would no longer want the GeneSight test. FE 3 stated that, since GeneSight was not the least expensive genetic test, if other tests still analyzed more medications than GeneSight, doctors would choose those instead.

135. The change to GeneSight the FDA "demanded" in July 2019 – that Myriad change GeneSight so that it no longer recommended specific medications – would have a devastating impact on the test's marketability and primary value proposition: specific medication selection guided by the test's "proprietary" algorithm. While Myriad charges Medicare more than $2,000 for GeneSight's psychotropic panel, if the FDA prevented GeneSight from recommending specific medications, the test would simply be a multi-gene test panel, which competitors market for ***$200-$300 per test***. Thus, the changes to GeneSight demanded by the FDA were highly material, as Myriad's reimbursement for GeneSight would likely be reduced by 90% or more.[11]

136. Despite knowing that the FDA had expressed serious concerns that Myriad's claims about GeneSight's efficacy were unsupported and had requested that highly significant,

[11] Notably, ACLA's publication of its openly hostile letter to the FDA indicates that Myriad had been unable to persuade the agency that changes to the test were unnecessary. After all, if Myriad's dialogue with the agency were positive, there would be no need to publish a letter challenging the FDA's ongoing review.

financially devastating, changes be made to the test offering, Defendants continued to misleadingly tout GeneSight to investors and the public.

D. Defendants Took Advantage of Myriad's Inflated Share Price to Dump Millions of Dollars' Worth of Myriad Stock

137. On August 1, 2019 – at the same time that the FDA was privately expressing grave concerns about GeneSight to Myriad and after the Company withdrew two of GeneSight's key panels because they lacked adequate scientific support, and the day after Myriad internally announced it would be pulling 32 medications from the GeneSight offering -- Myriad announced highly positive news for GeneSight: UnitedHealthcare, one of the country's largest insurers, would cover GeneSight. In response to this news, Myriad stock skyrocketed by 55%. On the same day, Capone sold ***31%*** of his Myriad stock holdings and Riggsbee sold ***10%*** of his holdings in a ***single*** pre-planned transaction at artificially inflated stock prices, reaping more than $6 million and $1 million in proceeds, respectively.

138. Defendants' August 1, 2019 announcement failed to disclose what Defendants had long known, however: that Myriad had been forced to drop GeneSight's ADHD and analgesic panels due to inadequate evidence of efficacy and that the FDA was scrutinizing GeneSight's psychotropic panel and had requested that Myriad make changes to the test that would eviscerate its marketability. As discussed above, when Myriad finally disclosed these highly adverse facts just two weeks later, the Company's stock ***plummeted by 42%***. The below figure reflects the response of Myriad's stock price to these announcements:

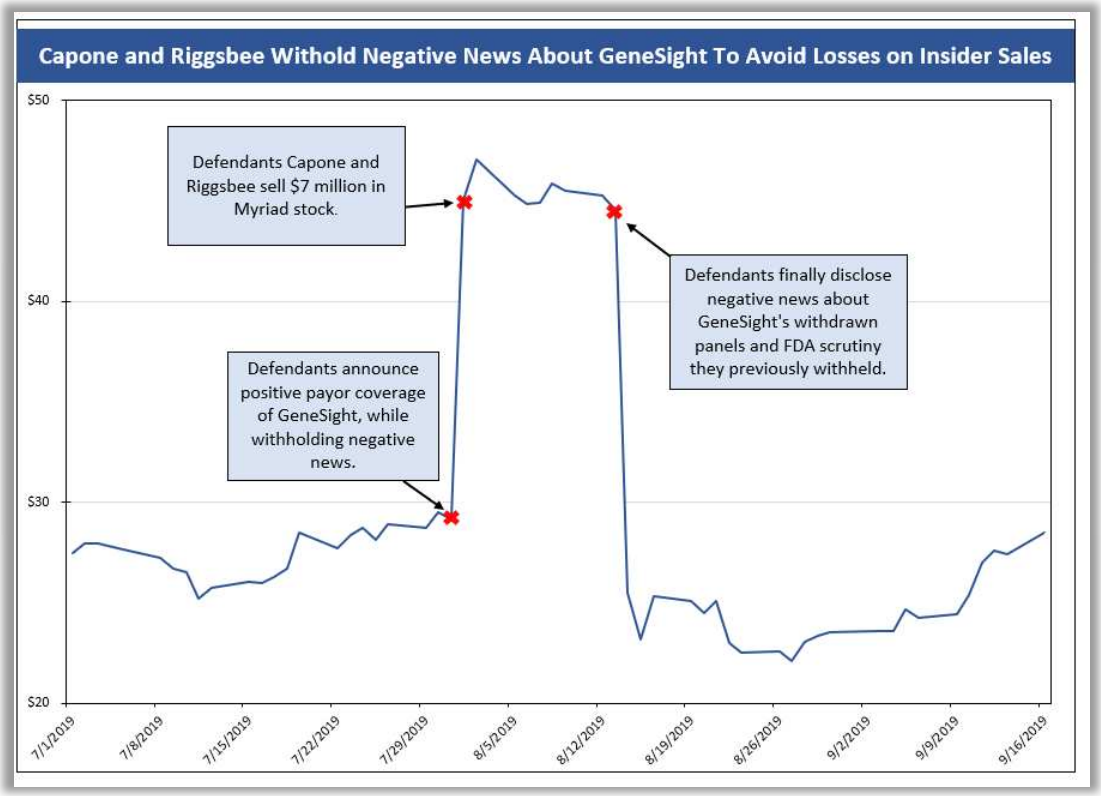


Figure 4. Defendants Capone and Riggsbee manipulated Myriad's disclosures and withheld negative news about GeneSight in order to avoid losses on millions of dollars' worth of pre-planned stock sales.

139. That Myriad conveniently rushed to broadcast highly positive news about GeneSight to the market just before Capone's and Riggsbee's pre-planned August 1, 2019 sales, while conveniently delaying disclosure of highly negative news about GeneSight that had long been in the Company's possession until shortly after those pre-planned sales, benefitted Capone and Riggsbee enormously. Had Capone's and Riggsbee's sales been executed after the Company's disclosure of negative GeneSight news just two weeks later, their proceeds would have been slashed almost in half.

E. Myriad Overstated Its Revenue During the Class Period

140. By the beginning of 2019, Myriad's reliable hereditary cancer revenue stream, already a bulwark of the Company's cash flow, took on exponentially more significance to the

Company and its investors. As discussed above, on October 31, 2018 the FDA issued a public Safety Communication raising questions about the accuracy and safety of pharmacogenetic tests like GeneSight and casting doubt on Defendants' statements about the strength of the evidence supporting the effectiveness of GeneSight. Moreover, unknown to investors, a panel of outside experts had privately told Myriad that, contrary to Defendants' statements, GUIDED did not offer meaningful clinical support for GeneSight's efficacy. Accordingly, as GeneSight's commercial viability continued to unravel during the Class Period, Myriad's backstop of hereditary cancer revenue became increasingly important. Indeed, as discussed above, analysts viewed the Company's hereditary cancer revenue stream as providing an essential lifeline to Myriad as it worked to grow its key growth product, GeneSight.

141. Unfortunately for Myriad, however, by the beginning of 2019, commercial and competitive pricing pressures affecting the Company's hereditary cancer business came to a head. Rather than address these issues head-on, Myriad, facing significant pressure from the slow collapse of GeneSight, overstated revenue attributable to its hereditary cancer test during the Class Period, as the Company ultimately admitted on its November 4, 2019 earnings call. On that call, Myriad disclosed that as a result of its overstatement of hereditary cancer test revenue it had been forced to take an $18 million out-of-period adjustment, and, more importantly, to lower its revenue accrual model by at least 8% going forward. Notably, but for the Company's overstatement of at least $7 million in hereditary cancer revenue in the third fiscal quarter of 2019 (the three months ended March 31, 2019), the Company would have reported an earnings loss for the quarter. The Company's misleading revenue accrual, however, allowed the Company to instead report a $7 million gain.

142. During the Class Period, Myriad's hereditary cancer test was beset by serious competitive and pricing pressures, and the Company faced significant pressure from investors to maintain the test's lucrative revenue stream and demonstrate its durability. Myriad first marketed its hereditary cancer test in the mid-1990s at a hefty price of $3,000 per test. However, a slew of competitors quickly emerged offering genetic screening for hereditary cancer, including breast and ovarian cancer, at prices far below Myriad's. This competitive pressure came to bear on Myriad's hereditary cancer test through a series of changes to Medicare billing codes that had a negative impact on pricing. As discussed below, Myriad nonetheless made unsupported revenue assumptions in violation of Generally Accepted Accounting Principles ("GAAP") to disguise this pricing pressure until the Company was ultimately forced to correct and disclose its misconduct.

143. Federal regulations require Myriad to bill government programs for reimbursement using standardized codes. Through at least 2016, Myriad billed for its hereditary cancer test by "stacking" two codes[12] – 81211 and 81213 – for testing for mutations in BRCA1 and BRCA2 genes that increase the risk of breast and ovarian cancer. In 2016, the Center for Medicare and Medicaid Services ("CMS") merged these two codes into a single new code, 81162, which was priced at $2,200, 10% lower than the two "stacked" codes Myriad had previously used to bill for its test. Myriad claimed it stopped using the 81211 and 81213 codes in 2016 and had shifted to billing for its hereditary cancer under the new code, 81162.

144. Over time, technical advancement and marketplace dynamics allowed the use of large-panel tests that screen for genetic variations associated with different types of cancer to become widespread. The proliferation of large-panel screening encouraged new entrants into the

[12] Code "stacking" refers to the practice of billing separately for each discrete step performed as part of a lab test.

genetic testing marketplace, further driving prices down. CMS responded to this increased competition in 2017 by introducing yet another pair of billing codes, 81432 and 81433, for multi-gene screening to be reimbursed at less than $1,400 combined. Myriad, however, petitioned CMS to be able to continue to bill under the 81162 code at the higher reimbursement rate, arguing that its test was vastly different from competitors' offerings.

145. Adding to the pricing pressure facing Myriad, the American Medical Association ("AMA") formally deleted the 81211 and 81213 codes beginning in January 2019 and replaced them with codes 81X78 and 81X79. The collective price for these two new codes, 81X78 and 81X79, is approximately $1,100, about half the $2,200 price for the 81162 code Myriad chose to continue to use. Notwithstanding this serious pricing pressure, Myriad continued to assure investors that the Company was confident in its ability to continue to seek reimbursement for its hereditary cancer under the favorable 81162 code.

146. Although the 81211 and 81213 codes had become obsolete in 2016, they remained in Myriad's contracts with more than 1,000 payors. Rather than revise these payor contracts, Myriad "notified" contracted payors of the code changes and that Myriad intended to "cross-walk" its 81162 code "to the historical contract pricing." Moreover, for uncontracted payors, Myriad simply "assum[ed] . . . that these payors would cross-walk pricing to the Medicare clinical lab fee schedule for the" 81162 code. In other words, notwithstanding the proliferation of far less expensive candidates to replace the treatment codes retired by the AMA, Myriad selected the most expensive replacement and booked revenue on the assumption that all of its payors would categorically accede to this unilateral decision.

147. However, Myriad never verified its extravagant assumptions through communications with these payors, and, instead, booked and reported hereditary cancer revenue

as though all payors had agreed to use the 81162 code and to "cross-walk" it to the Company's historical pricing, notwithstanding the significant revisions in coding and pricing promulgated by both CMS and the AMA. By its own admission, Myriad simply "assumed" that subsequent coding revisions resulting in far lower reimbursement for hereditary cancer tests would have no impact on payors' willingness to "crosswalk" their billing codes to the much more expensive 81162 code. In violation of longstanding GAAP principles, Myriad failed to make changes to its revenue accrual model to account for this uncertainty, or even disclose that it had not verified these important contingencies affecting the Company's reported revenue. As discussed above, the Company's overstatement of at least $7 million in hereditary cancer revenue in the third fiscal quarter of 2019 (the three months ended March 31, 2019), allowed the Company to avoid reporting an earnings loss, and instead report a $7 million gain.

148. Myriad further admitted that by no later than the fourth fiscal quarter of 2019 (the three months ended June 30, 2019), the Company observed a significant increase in the number of denied claims and "short" payments for its hereditary cancer tests. Numerous payors were using the code change to refuse or significantly discount payment for Myriad's hereditary cancer tests – a fact Defendants would have readily discovered from the outset had they contacted payors, instead of improperly "assuming" they would all agree to the coding and fee schedule changes. As Capone admitted on Myriad's November 4, 2019 earnings call, Myriad knew that payor reimbursement was not "consistent with our revenue accrual rate assumption."

149. Yet, even at this point, Defendants still failed to disclose that payors were using the changed coding as an opportunity to seek lower pricing of, and even refusing to cover, Myriad's key product, and the highly material uncertainties and dubious assumptions underlying the Company's revenue accrual. As a result, Myriad reported inflated revenue during the Class

Period, and, as discussed above, would be forced to adjust its prior reported revenue and its revenue accrual model downward.

150. Myriad's failure to revise its reported revenue and disclose the change in payor behavior violated GAAP. GAAP standards, including ASC 450-30-20, prohibited Myriad from recognizing "gain contingencies" as revenue. A gain contingency is "[a]n existing condition, situation, or set of circumstances involving uncertainty as to possible gain to an entity that will ultimately be resolved when one or more future events occur or fail to occur." Accordingly, it was improper under GAAP for Myriad to book and recognize hereditary cancer revenue on the assumptions that (1) payors would consent, without question, to the Company's unilateral decision to replace its obsolesced billing codes with the most expensive alternative; and (2) the significant increase in denied and short-paid claims would reverse itself.

151. In addition, GAAP required Myriad to provide "[a]dequate disclosure" of any gain contingency reflected in the Company's financial statements "that might result in a gain, but care shall be exercised to avoid misleading implications as to the likelihood of realization." ASC 450-30-50-1. Here, at a minimum, it was misleading, and impermissible under GAAP, for Myriad to fail to disclose the significant uncertainties underlying the gain contingencies reported in the Company's financial statements. Indeed, not only did Myriad's financial reporting mislead investors "as to the likelihood" that payors would accept Myriad's selection of the most expensive billing code for its hereditary cancer test ***and*** reverse their denials and short-payments of such claims, the Company did not disclose that revenue booked on these assumptions was contingent ***at all***.

152. Finally, Myriad's accrual of variable revenue (including third party payor reimbursements) attributable to its hereditary cancer test was governed by ASC 606, which provides:

> ***At the end of each reporting period***, an entity shall update the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent ***faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period***.

See ASC 606-10-32-14. Thus, Myriad's "hope-for-the-best" approach to its hereditary cancer revenue, in which it improperly assumed revenue would remain at, or return to, historical levels despite changed circumstances, was wholly impermissible under GAAP, and materially false and misleading as a result.

153. Significantly, in November 2018, Myriad previously reported a prior material weakness in its internal accounting controls over revenue accrual – the same process through which Myriad later overstated its hereditary cancer revenue. Specifically, in its first quarter 2019 (ended September 30, 2018) Form 10-Q (filed on November 7, 2018), signed by Capone and Riggsbee, Myriad stated:

> As of September 30, 2018, we are in the process of remediating the material weakness over financial reporting ***related to insufficient controls to fully and timely take into account changes in the business environment and experience with ultimate collection from third-party payors in the determination of sales allowance amounts***; however, the material weakness cannot be considered remediated until the deficient controls have been tested for effectiveness.

In other words, Myriad understood that its model for reporting revenue did not "fully and timely take into account" actual payor behavior.

154. However, in its very next quarter filing – the Company's second quarter FY 2019 (for the three months ended December 31, 2018) Form 10-Q (filed on February 6, 2019), signed by both Capone and Riggsbee, Myriad claimed that this control deficiency "***has been sufficiently***

remediated" as of December 31, 2018. Moreover, in signed certifications appended to the Form 10-Q, Capone and Riggsbee stated that they "evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures." Moreover, both Capone and Riggsbee certified that Myriad's Form 10-Q disclosed "all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information." Myriad ***again*** confirmed in the Company's third quarter FY 2019 (ended March 31, 2019) Form 10-Q (filed May 8, 2019) that the material weakness had been resolved.

155. Accordingly, Capone's and Riggsbee's signed certifications reassured investors that they were both ***highly*** focused on Myriad's revenue accrual process, and, in particular, ensuring that its failure to "fully and timely take into account" actual payor behavior had been remediated at the very time that Myriad was overstating its hereditary cancer revenue. As such, Defendants' statements inflating Myriad's hereditary cancer revenue, which failed to "fully and timely" disclose the Company's extravagant assumptions and historical observations about payor behavior, as well as their subsequent internal control certifications, were made recklessly at a minimum.

F. The Truth Gradually Emerged

1. The FDA's October 31, 2018 "Safety Communication" Raised Questions About GeneSight's Efficacy

156. The market first began to learn the truth about the dearth of empirical and clinical support for GeneSight's efficacy, and flimsiness of the support for the test offered by the GUIDED study, on October 31, 2018. As discussed above, Myriad had been engaged in a vigorous campaign to expand payor coverage and physician adoption of GeneSight. However, that day,

after the market closed, the FDA publicly issued a Safety Communication titled, "The FDA Warns Against the Use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications." The FDA's Safety Communication began to reveal to investors that, contrary to Defendants' claims, GeneSight was not "clinically proven" to effectively match patients to specific medications and, in particular, that the test's efficacy was not supported by strong clinical evidence meeting "FDA guidance" and standards for evidentiary soundness.

157. The FDA's Safety Communication stated that it was focused on "Genetic laboratory tests with claims to predict a patient's response to specific medications, that have not been reviewed by the FDA and may not be supported by clinical evidence." As an example of such tests, the FDA's Safety Communication specifically cited "genetic tests that claim results can be used to help physicians identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications," just like GeneSight's psychotropic panel. The Safety Communication made clear that the FDA was skeptical that pharmacogenetic tests, in general, were supported by clinically validated evidence of efficacy and, in particular, did not believe that ***any*** evidence of gene-drug connection had been established with respect to antidepressants. Moreover, the Safety Communication cautioned that physicians following recommendations made by pharmacogenetic tests had made "inappropriate," potentially dangerous, changes to their patients' medication, and warned other physicians against repeating these mistakes:

> However, ***the relationship between DNA variations and the effectiveness of antidepressant medication has never been established***. The FDA is aware that health care providers may have made inappropriate changes to a patient's medication based on the results from genetic tests that claim to provide information on the personalized dosage or treatment regimens for some antidepressants. ***Patients and health care providers should not make changes to a patient's medication regimen based on the results from genetic tests that claim to predict a patient's response to specific medications, but are not supported by scientific or***

> ***clinical evidence to support this use***, because doing so may put the patient at risk for potentially serious health consequences.

158. In addition, the FDA urged doctors considering using any pharmacogenetic test ***not*** to rely on any therapeutic recommendations made by the test, but to consult the drug's FDA-approved label, thereby eroding GeneSight's key value proposition, *i.e.* its bucketing of drugs into recommended/not recommended categories:

> If you are using, or considering using, a genetic test to predict a patient's response to specific medications, be aware that for most medications, the relationship between DNA variations and the medication's effects has not been established. Check the FDA-approved drug label, or the label of the FDA-cleared or approved genetic test for information regarding whether genetic information should be used for determining therapeutic treatment.

Thus, the FDA raised questions about whether GeneSight added any clinical value beyond a simple multi-gene screening test that cost a fraction of the price. Though the FDA did not explicitly prohibit test manufacturers from marketing products that made specific drug recommendations, it raised serious questions about their therapeutic, and therefore economic, value.

159. At 8:20 a.m. the next morning (before markets opened), FDA Commissioner Scott Gottlieb tweeted out the Safety Communication.

160. Also on November 1, 2018, Dr. Jeffery Shuren, the head of the FDA's Center for Devices and Radiological Health and Dr. Janet Woodcock, the head of the FDA's Center for Drug Evaluation and Research, both issued a joint statement reiterating the warnings appearing in the FDA's Safety Communication the previous day. The joint statement made clear that the Safety Communication was a collaboration between these two powerful departments and, as such, reflected a broad consensus about the appropriate regulatory approach to pharmacogenetic testing. Moreover, the statement once again emphasized the FDA's skepticism about the claim of some tests to make ***specific*** recommendations about appropriate drug therapies. In particular, the

statement noted that while the FDA had recently approved tests that identify genetic variants that may play a role in drug metabolism, "we have required that the test label make clear that it is not intended to provide information on a patient's ability to respond to any specific medication."

161. Investors and analysts were troubled by the FDA's warnings and recognized that they were in tension with Defendants' statements about the manner in which GUIDED had been conducted and the extent to which its results supported the efficacy of GeneSight's psychotropic panel. For instance, Barclays analysts issued a November 1, 2018 report, in which they stated, "Following the FDA's announcement this morning we also now see new risks related to [GeneSight's] volume trajectory." The analysts underscored that the FDA's concern, as expressed in the Safety Communication, appeared to be focused on tests that, like GeneSight's psychotropic panel, claimed to be able to predict patient response to antidepressants. The Barclays report stated, "Importantly for GeneSight, the FDA highlighted, 'Genetic tests with claims to predict whether some medications used to treat depression may be less effective or have an increased chance of side effects.' Myriad's GeneSight is one of several tests in a category of pharmacogenetics used for patients with treatment-resistant depression." Similarly, in a November 7, 2019 report, Barclays analysts elaborated, "[W]e continue to believe the FDA warning on pharmacogenetic testing in depression could raise risks for GeneSight coverage and volumes as well. We believe given the profile of the announcement, it will likely be raised to CMS' attention – posing risks for non-coverage of the test."

162. In reaction to this news, Myriad stock declined by more than 12.5%, falling from $45.03 at the close of market on October 31, 2018 to $39.40 at the close of market on November 1, 2018, on the year's highest volume.

163. In order to allay investor concern, Defendants amplified their false and misleading statements about GeneSight and the GUIDED trial, emphasizing that GUIDED had been rigorously conducted pursuant to FDA guidance, provided highly robust clinical evidence of GeneSight's efficacy, and would insulate Myriad's product from adverse FDA action. For instance, on the Company's November 6, 2018 earnings call, Capone stated that the FDA was "well aware that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has clear clinical evidence demonstrating improved patient outcomes, [and] that that difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing." As discussed above, these statements were materially false and misleading.

164. As Defendants intended, analysts credited their soothing statements. For instance, in a November 1, 2018 report, Stephens analysts stated, "The FDA cites as examples genetic tests that predict how a patient will respond to medications for depression, heart conditions, acid reflux, etc . . . . We believe Genesight specifically - via its 1200 patient GUIDED trial - has validated claims (despite no FDA approval)." Likewise, following Defendants' November 6, 2018 reassurances, these same analysts stated in a November 9 report, "the FDA issued a notice for pharmacogenomic testing cautioning providers/patients about using tests that are not backed up by clinically validated evidence . . . . Ultimately, ***MYGN wins*** if an environment evolves that requires more validations and stepped up regulatory oversight."

2. At a January 4, 2019 Investor Conference, a Prominent Psychiatrist Impugned Defendants' Claims That GUIDED's Results Showed GeneSight Was Effective

165. As discussed above, following the FDA's October 2018 Safety Communication, Defendants succeeded in assuaging the market's concerns about GeneSight's efficacy, and worries over potential adverse regulatory action, by assuring investors that the GUIDED study

had been conducted and reported "consistent with the FDA's guidance on clinical trials for depression" and offered singular support for the efficacy of Myriad's key pharmacogenomic test. As discussed above, on January 4, 2019, Defendants further reassured investors through the publication of the GUIDED study results in the *Journal of Psychiatric Research*. Myriad's publication misleadingly touted the results of the Company's secondary endpoint and post-hoc analyses, taking care to reiterate that GUIDED had been conducted "in line with the recent FDA draft guidance for MDD [major depressive disorder] trials."

166. After the close of the market on January 4, 2019, and following the publication of the GUIDED paper, investors learned additional facts undermining Defendants' claims about GeneSight and the evidence supposedly supporting it. Specifically, Barclays analysts hosted an investor call with prominent psychiatrist Dr. Charles Nemeroff to discuss the recently published GUIDED results. On this January 4 call, investors learned additional facts further undermining Defendants' claims that the GUIDED study provided strong empirical support for GeneSight and could shield the test from FDA scrutiny. In particular, on this call Dr. Nemeroff stated that the "salient and most important finding in this study is the fact that it's a failed study, that . . . the primary hypothesis in this study, which is that pharmacogenomic testing would impact clinical outcomes, the primary outcome measure failed to show any difference . . . . It was actually not even close to being significant." Further, Dr. Nemeroff explained that "once your primary outcome measure is not realized, then ***all of your secondary data analysis, it really isn't valid***." Indeed, Dr. Nemeroff pointed out that in any clinical trial, if "the primary outcome measure isn't met, it's ***never approved by the FDA***, regardless of what the secondary outcome measures might show."

167. On January 7, 2019, Barclays analysts issued a report repeating and crediting Dr. Nemeroff's statements. The analysts noted that Dr. Nemeroff "is an important thought leader who chaired the [American Psychiatric Association] Task Force on Novel Biomarkers and Treatments." The Barclays analyst report further credited Dr. Nemeroff's comments that the number of secondary endpoints Myriad explored cast doubt on the meaningfulness of the results of those analyses and repeated Dr. Nemeroff's statement that "Once your primary outcome measure is not realized, then all of your secondary data analysis, it really isn't valid." Finally, the analysts pointed out that Myriad had failed to disclose important facts about GUIDED to investors:

> The publication timeline on the cover of the manuscript is inconsistent with Myriad's public commentary, given the journal says it was originally received on 8/20/2018. The first page of the GUIDED study says that it was received by the Journal of Psychiatric Research on 8/20/2018, it was revised on 11/13/2018, and it was accepted on 1/2/2019. On Myriad's FY4Q18 conference call on 8/21/2018, the company made no note that it had switched journals for the publication. In fact, CEO Capone stated that the study was in the "latter stages of review," where in actuality, the study was on Day 2 of review at the Journal of Psychiatric Research. Myriad did not disclose that they had switched journals until FY1Q19 earnings of 11/6/2018.

168. Likewise, the *Southern Investigative Reporting Foundation*, a foundation devoted to financial investigative reporting, published a January 7, 2019 article, titled "*Myriad Genetics: This Company Has Great Difficulties Telling the Truth*, reporting and crediting Dr. Nemeroff's statements on the January 4, 2019 Barclays call. The article stated:

> Dr. Nemeroff described the trial as unsuccessful. "The most salient and most important finding in this study is the fact that it's a failed study," he said, adding that GeneSight's benefit for patients, as measured in the trial, "wasn't even close to being significant."
>
> During this call, Myriad chose to defend GeneSight's merits in a highly unusual fashion, however. Its director of clinical development, Bryan Dechairo, spoke up on the call 30 minutes in and after reading a prepared statement, started peppering Dr. Nemeroff with questions; he even tried to query him about a 2006 medical study mentioned in passing. Dr. Nemeroff, who had been politely answering all

> Dechairo's questions, quietly informed him that the premise of his last one "doesn't hold water."
>
> Two portfolio managers told the Southern Investigative Reporting Foundation that they had never seen a public company's representative do something like this on an analyst's client call.

169. In response to these disclosures, the Company's stock fell by nearly 11% from $31.32 at the close of market on January 4, 2019 to close at $27.98 on January 7, on high trading volume.

170. Nevertheless, Defendants continued to issue false and misleading statements about GeneSight's efficacy and the strength of GUIDED in order to allay the market's concerns, including fears of adverse regulatory action. In particular, Defendants specifically sought to discredit Dr. Nemeroff's assertions on multiple fronts. *First*, during the Barclays call's question and answer session, Defendant Dechairo dialed in, purporting to ask questions of Dr. Nemeroff, but, in reality, continued to make misleading assertions that Myriad's post-hoc analyses demonstrated that GeneSight had shown statistically significant improvement in supposedly "key" endpoints.

171. *Second*, following the Barclays call with Dr. Nemeroff, Myriad's Senior Vice President of Investor Relations and Corporate Strategy, Scott Gleason, sent a select group of asset managers and securities analysts an email asserting that Dr. Nemeroff's statements on the Barclays call were incorrect and inaccurate. Among other things, Myriad's email stated that Dr. Nemeroff's statement that GeneSight had failed to achieve GUIDED's primary endpoint of statistically significant symptom improvement was "misleading." Myriad countered by stating, "In the PHQ-9 data . . . we achieved statistical significance for symptom improvement. Likewise, Myriad claimed that "Dr. Nemeroff incorrectly stated that there was no difference in side effects between on red medications in the study." Myriad misleadingly cited its invalid post-hoc

congruent/incongruent patient analysis claiming that a statistically significant difference in side effects was found in that subgroup.

172. *Finally*, two hours after the Barclays investor call, Myriad hosted its own investor call and reiterated its misleading statements touting Myriad's improper post-hoc analyses, and asserted that the response and remission results were far more clinically meaningful than the failed symptom improvement endpoint. For instance, Dechairo presented yet another improper post-hoc analysis to investors – one which, as discussed above, excluded all patients who entered the study on "green medication," and falsely claimed that "all 3 endpoints were statistically significant" in this subgroup. Dechairo stated, "This analysis clearly demonstrates that GeneSight improves outcomes for the 70% of patients taking medications that require modification based upon their genetic profile."

173. As discussed above and in further detail below, these statements were materially false and misleading when made. Among other things, when the secondary and post-hoc endpoints touted in Myriad's email and on the Barclays and Myriad investor calls are analyzed as required by Myriad's own clinical trial protocol, the results are ***not*** statistically significant, contrary to Myriad's claims. Moreover, under the FDA guidance Myriad claimed to follow, the results of these analyses are clinically meaningless because that guidance provides that "[p]ositive results on the secondary endpoints can be interpreted ***only*** if there is first a demonstration of a treatment effect on the primary endpoint family." Indeed, unbeknownst to investors, Myriad's own scientists agreed that the Company's post-hoc analyses and selective focus on secondary endpoints were just a "fishing expedition," a "sham" and "arbitrary," and a panel of independent peer-reviewers at the prestigious *American Journal of Psychiatry* had reiterated this warning.

174. Nevertheless, Defendants' soothing statements were effective in tempering the market's reaction to the Barclays investor call. For instance, in a January 6, 2019 report, Piper Jaffray analysts repeated Defendants' misstatements that GeneSight "met the secondary endpoints of response and remission" in GUIDED and credited Myriad's misleading post-hoc analyses, stating they "suggest[] a pronounced improvement when patients on incongruent drugs were changed to congruent ones."

3. On August 13, 2019, Myriad Shocked Investors by Finally Disclosing the Discontinuation of GeneSight's ADHD and Analgesic Panels and FDA Scrutiny of the Psychotropic Panel

175. After the market closed on August 13, 2019, Myriad held its fourth quarter and full-year 2019 earnings call (for the quarter ended June 30, 2019). After repeatedly assuring investors about GeneSight's efficacy for nearly three years, Myriad shocked the market by disclosing on that call that by no later than May 2019, Myriad had withdrawn GeneSight's ADHD and analgesic panels. Myriad finally acknowledged that, contrary to Defendants' repeated statements during the Class Period, GeneSight's ADHD and analgesic panels were not supported by adequate evidence and, as a result, payors had refused to reimburse for administration of these panels and even declined to offer coverage of GeneSight generally. Defendant Riggsbee stated:

> In May, we made the decision to discontinue our analgesic and ADHD products because . . . the level of clinical evidence did not meet the same high standard set by the GeneSight psychotropic test in the GUIDED study. In addition, a few payers expressed similar views, and we wanted to eliminate any potential hurdles to commercial payer coverage for GeneSight psychotropic.

176. Moreover, as discussed above, Myriad further disclosed that because the ADHD and analgesic panels were substantial drivers of overall demand for GeneSight, discontinuation of these panels had significantly impacted the Company's GeneSight revenue, including by reducing demand for GeneSight's psychotropic panel. Specifically, Riggsbee stated that "there was a collateral impact of the GeneSight psychotropic orders from ADHD and analgesic ordering

physicians. The net effect was a 15% reduction in GeneSight revenue in June, which we expect to continue into the first quarter . . . . [R]evenue in the first quarter will reset to a lower base following the discontinuation of the analgesic and ADHD test." Notably, Myriad stated that discontinuation of the ADHD and analgesic panels would negatively impact volumes for United Healthcare, tempering the positive news Defendants had selectively released just before their massive insider sales two weeks earlier.

177. On that same August 13, 2019 earnings call, Myriad revealed that "[e]arlier in 2019," but unbeknownst to investors, the FDA had privately told the Company that the evidence it had submitted to the agency in support of GeneSight's psychotropic panel, including the GUIDED study, was not adequate, and requested that Myriad make changes to "the GeneSight test offering." Specifically, Riggsbee acknowledged, "earlier in 2019, we provided the FDA with clinical evidence and other information to support our GeneSight psychotropic test. More recently, the FDA requested changes to the GeneSight test offering, and we have been in ongoing discussions with the FDA regarding its request." The market was further surprised by this news and understood that it seriously undermined Defendants' statements touting GeneSight's "clinically proven" efficacy and the results of the supposedly FDA-guideline-compliant GUIDED study.

178. Analysts were shocked and troubled by Myriad's disclosures. Barclays analysts issued an August 14, 2019 report downgrading Myriad to "Underweight," highlighting that "the company is in discussion with the FDA to make changes to the GeneSight test report, which we think could compromise the test's value proposition." These analysts also reported that GeneSight faced "headwinds related to the discontinuation of the GeneSight ADHD and Analgesic."

179. Importantly, the Barclays analysts made clear that Defendants had not been honest and transparent with investors. First, the analysts expressed their "surprise" that Defendants had announced the positive UnitedHealth coverage decision two weeks earlier while withholding highly material negative facts: "In the context of Myriad's 8/1/2019 8-K disclosure around UnitedHealth coverage of GeneSight, ***we are surprised the company did not also pre-announce earnings given the materiality of the miss and FDA dialogue***." Second, in a subsequent report, Barclays analysts also specifically highlighted Capone's November 2018 statement that the FDA was "***well-aware*** that [GeneSight] has clear clinical evidence demonstrating improved patient outcomes" and contrasted it with the Company's August 2019 disclosures that, in truth, the FDA did not credit Myriad's supposedly "clear clinical evidence" and had asked the Company to make significant changes to GeneSight.

180. Likewise, in an August 13, 2019 report, Leerink analysts wrote that Myriad had hit investors with "a number of negative surprises." These analysts stated, "This quarter brought another surprise as MYGN reported that the FDA is further scrutinizing its pharmacogenomics testing and requesting changes to the GeneSight test . . . . Further, MYGN made a decision in May to discontinue its ADHD and analgesic offerings of GeneSight as they did not meet the stds [standards] of GUIDED study. Net impact was 15% GeneSight revenue reduction in June, expected to continue into F1Q20." Cowen analysts similarly stated in an August 14, 2019 report that GeneSight revenue missed estimates as a result of "the negative impact of withdrawing analgesic/ADHD testing from the GeneSight menu," which the analysts reported "is expected to pressure near-term revenues." Moreover, like the Barclays analysts, Cowen's report also pointed out that the Company's disclosures "seemingly countered a lot of the momentum" Myriad had coming off of the "highly anticipated UNH [UnitedHealthcare] coverage decision for GeneSight."

181. In an August 13, 2019 report, Deutsche Bank analysts lowered their price target for Myriad by 22% "to reflect lower forecasted market penetration for MYGN's GeneSight test." The analysts reported, "Due to a lack of high-quality clinical evidence, MYGN discontinued its GeneSight ADHD and analgesic products in May. This resulted in a 15% reduction in GeneSight revenue in June" and that "FDA requested changes to GeneSight test reporting." Similarly, in an August 14, 2019 report, Jeffries analysts stated that Myriad's disclosures created "more uncertainty around GeneSight (FDA scrutiny). We think this remains a show-me stock until GeneSight visibility improves." In particular, these analysts highlighted that "MYGN discontinued GeneSight's analgesic and ADHD offerings in May, which led to a -15% [GeneSight] rev [revenue] decline (expect to [continue] in 1Q20)" and FDA action that would "require PGx [pharmacogenetic] tests to remove specific drug recommendations from test reports."

182. Finally, J.P. Morgan analysts reported on August 13, 2019 that "GeneSight [revenue] ***declined*** 12% y/y, due to discontinuation of analgesic/ADHD products (on subpar clinical evidence)." (emphasis in original). These analysts further stated that, given Myriad's disclosures, "key questions around GeneSight remain unaddressed, in light of recent FDA interactions" and recent agency actions "that require the removal of specific drug recommendations from PGx testing reports," which the analysts believed "could ***significantly*** limit the broader adoption of GeneSight among PCPs and community psychiatrists." (emphasis in original). The analysts further pointed out Capone's and Riggsbee's suspicious stock sales: "[W]e also note the ***>$10 million in insider selling*** (under 10b-5) that occurred on 8/1." (emphasis in original).

183. In response to Myriad's August 13, 2019 disclosures, the Company's stock plummeted $19.05 per share, or ***42.76%***, to close at $25.50 per share on August 14, 2019 on the second-highest trading volume of the year.

184. Yet again, however, Defendants continued to issue false and misleading soothing statements to the market in order to assuage investor concern. For instance, Capone hyped Myriad's improper post-hoc analysis of the GUIDED data excluding patients entering the study on "green medications," falsely claiming it showed "statistically significant improvement" on all endpoints.

185. And, again, analysts continued to credit Defendants' misleading statements. For instance, in an August 14, 2019 report, BTIG analysts stated, "Looking ahead, GeneSight remains the crux of our Buy thesis, with MYGN barely having scratched the surface of the significant [market] and at an inflection point of garnering meaningful private payer coverage expansion . . . We believe with the unprecedented amount of clinical evidence generated for GeneSight, GeneSight is well-positioned both competitively as well as from regulatory scrutiny, and could drive high single digit total revenue growth for MYGN over the next 18-24 months." Likewise, Piper Jaffray analysts also continued to parrot Defendants' false statements that GUIDED would shield GeneSight from adverse FDA action: "We believe Myriad's GUIDED data is superior than competitors, which could enable them to retain their green/yellow/red drug guidance (and potentially have a significant competitive advantage) . . . . GUIDED Data is the Shining Light. GeneSight has significantly more supporting evidence than most PGx tests, and Myriad has provided this information to the FDA."

4. On November 4, 2019, Myriad Disclosed That It Had Been Overstating Its Hereditary Cancer Test Revenue

186. On its November 4, 2019 earnings call (reporting the Company's first quarter 2020 earnings), Myriad further shocked investors by revealing that, in addition to the unraveling of GeneSight's once bright growth prospects, Myriad's seemingly reliable hereditary cancer revenue was now also facing financial adjustments. Specifically, on its November 4 call, Myriad acknowledged that it had been experiencing a significant increase in the number of denied and partially unpaid claims for the Company's critical hereditary cancer test as a result of the AMA's change in billing codes discussed above, and had overstated revenue attributable to the test during the Class Period. Specifically, Capone reported a "significant[]" revenue miss, "largely related to revenue adjustments associated with hereditary cancer testing . . . . The root cause of this shortfall was driven by the deletion of the 81211 and 81213 codes beginning on January 1, 2019," which "had been included in [Myriad's] payor contracts since 2012." As discussed above, Capone told investors that, rather than revise their payor contracts, Myriad's contracted payors were "notified" of the Company's "intent to crosswalk the new code to the historical contract pricing." Moreover, Capone admitted that for non-contracted payors, Myriad simply "assum[ed] . . . that these payors would cross-walk pricing to the Medicare clinical lab fee schedule for the new codes," and booked revenue "consistent with these assumptions."

187. Capone further admitted that during the fourth fiscal quarter of 2019 (the three months ended June 30, 2019), Myriad "noticed that payments were not always consistent with our revenue accrual rate assumption. In fact, in some cases, claims were being denied entirely despite the fact that these payers had reimbursed claims for many years." As discussed above, even at this point, Defendants still failed to disclose that payors were seeking lower pricing of,

and even refusing to cover, Myriad's key product, and the highly material uncertainties and dubious assumptions underlying its revenue accrual.

188. Capone disclosed that Myriad had finally been forced to take an $11 million out-of-period adjustment and, more importantly, lower its revenue accrual rate to be consistent with its "actual cash collection rate," reflecting payor pushback on Myriad's unilateral selection of the most expensive available billing code for its test by far. Capone stated, "We believe the prudent approach at this point is to assume that we will not be able to correct these administrative issues and our lowered revenue accrual rates are consistent with our actual cash collection rate." Myriad's lowering of its revenue accrual rate had a significant impact on Myriad's financials going-forward, resulting in an 8% reduction in Company-wide revenue estimates.

189. Finally, Myriad further disclosed mounting GeneSight revenue losses caused by the Company's removal of the test's ADHD and analgesic panels, amounting to a 25% loss in GeneSight revenue versus the prior year. These disclosures further indicated to the market that the evidence supporting GeneSight was far weaker than previously believed, since the payors and clinicians in a position to evaluate those claims were declining to adopt or cover GeneSight.

190. Analysts were again surprised and dismayed by Defendants' disclosures. Barclays analysts issued a November 5, 2019 report, stating:

> Myriad's FY1Q20 results were very weak, as ***new pricing pressure in the core hereditary cancer testing (HCT) franchise brings coding risks back to the forefront of the thesis*** . . . . The main focus was on an out-of-period adjustment to HCT [hereditary cancer test] accruals, which drove the majority of the miss. Specifically, Myriad called out an $11.2mm HCT adjustment related to revenues in FY2H19. Myriad's legacy HCT codes of 81211+81213 were deleted by the AMA to start 2019, and ***Myriad has been impacted by pricing reductions as commercial payors have updated their contracts***.

191. The Barclays analysts further wrote that "GeneSight revenues of $22.7mm missed our $27.5mm forecast, which was attributed to weaker volumes from the discontinuation of the

ADHD and Analgesic products in June 2019 . . . . Looking forward, Myriad is lowering its revenue forecast to account for lower contributions from both HCT [hereditary cancer testing] and GeneSight."

192. Likewise, on November 5, 2019, analysts from Jeffries reported Myriad's "surprise" announcement of new negative payor pricing pressure in connection with Myriad's hereditary cancer test, and discussed that the string of "negative surprises" called into question management's credibility:

> We expect MYGN to open down sharply (-30% after-hours) on the 1Q miss & slashed FY20 guidance, which mainly reflects the impact of lower cash collections for hereditary cancer tests from the ~20% of non-contracted payors (n=>1,000) related to CPT coding changes that took place on 1/1/19 . . . . ***With the latest negative surprise adding to a growing list of issues*** (including ongoing regulatory uncertainty for GeneSight, Prenatal ASP pressure), ***mgmt credibility is impaired*** & the pathway back to $2+ of EPS power is less clear.

193. In response to this news, Myriad's stock declined sharply, falling more than 40%, from $35.10 to $20.93 on November 4, 2019, on the year's highest trading volume.

5. On February 6, 2020, Myriad Shocked the Market by Announcing Defendant Capone's Sudden Resignation and Continued Over-Accrual of Revenue

194. On February 6, 2020, Myriad shocked investors by again announcing that Defendant Capone – who had been with Myriad for 17 years – was suddenly and unexpectedly leaving the Company. Specifically, on Myriad's fiscal second quarter 2020 earnings call (for the three months ended December 31, 2019), held after the market closed on February 6, Myriad told investors that Capone and Myriad's Board "mutually agreed" that Capone should resign from the Company "effective immediately". The Board's decision followed the Company's shocking disclosures concerning the Company's withdrawal of two of GeneSight's key panels, the FDA's request that the Company make commercially devastating changes to the remainder of the test, and Myriad's over-accrual of hereditary cancer revenue. Myriad further disclosed that Riggsbee

would be named interim-CEO while the Board searched for Capone's replacement, making clear that Capone's departure was not part of an orderly succession plan.

195. Notably, analysts on the call questioned Myriad management's credibility, suggesting that Capone's departure did not go far enough. A Cowen analyst asked Riggsbee, "Does a change of CEO go far enough? I know this is pretty direct, Bryan. And ***I don't mean to be rude, but I think it's fair to ask why investors should trust the broader management team and really largely the same Board of Directors that has been at the helm for the past decade?***"

196. In addition, Myriad disclosed that contrary to its bullish statements touting the UnitedHealth coverage decision as a watershed moment for GeneSight, Myriad was experiencing serious challenges obtaining reimbursement from the payor for administering the test and, as a result, there was almost no contribution to GeneSight sales from the coverage decision. Specifically, Myriad disclosed that it had a significant revenue shortfall, "well below our financial guidance for the quarter" due to "lower-than-anticipated GeneSight cash collections from UnitedHealthcare." Specifically, Myriad stated that UnitedHealth was denying and "short-paying" (*i.e.*, paying out at a smaller portion of billed charges, passing the balance to the patient) a highly significant number of claims. Myriad lowered its guidance for the remainder of fiscal 2020 from $810 million to $735 million, approximately 9%, to account for GeneSight's poor revenue contribution.

197. The market was shocked by Capone's sudden departure and understood that it signaled that the cornerstone of Myriad's growth strategy – GeneSight – was in even greater jeopardy than previously disclosed. Indeed, particularly given the Company's other disclosures, investors understood that the evidence for GeneSight was so weak that even UnitedHealth was now providing virtually no meaningful coverage for the test. For instance, in a February 7, 2020

report, Barclays analysts stated, "The biggest update was that CEO Mark Capone has resigned effective immediately, with CFO Bryan Riggsbee named interim CEO." These analysts further stated, "On the payor front, Myriad lowered expectations for the new UnitedHealth contract which covers GeneSight. Specifically, the company disclosed that a new prior authorization policy with UnitedHealth means there was almost no contribution to GeneSight sales from the coverage decision which started on 10/1/2019." Likewise, Jefferies analysts issued a February 7, 2020 report highlighting the "abrupt CEO departure . . . . Concurrent with the 2Q print, MYGN announced the abrupt resignation of CEO Mark Capone, who leaves the company after a 17-year tenure and 5 years as CEO." The analysts noted that Capone "oversaw much of MYGN's diversification push to shift the business away from hereditary cancer," including the acquisition and development of GeneSight, which had not "come close to hitting [its] deal models." Similarly, on February 6, 2020, J.P. Morgan analysts reported the "sudden departure of CEO Mark Capone," and that "GeneSight declined ~6% y/y, as a higher number of samples were declined through the UNH [UnitedHealth] pre-authorization process than the ~30% originally anticipated, coupled with a higher proportion of patient pay, driving a decrease in ASPs."

198. In response to this news, Myriad's stock declined more than 28%, from $29.29 at the close of market on February 6, 2020 to close at $21.02 on February 7, on high trading volume.

V. ADDITIONAL ALLEGATIONS THAT DEFENDANTS KNOWINGLY OR RECKLESSLY MISLED INVESTORS REGARDING MYRIAD'S KEY PRODUCTS AND FINANCIAL RESULTS

199. Numerous allegations set forth above collectively give rise to the strong inference that Defendants knowingly or at least recklessly misled investors about GeneSight's efficacy, the quality and character of the evidence supporting Myriad's claims about GeneSight's efficacy, and the Company's revenue, including revenue attributable to its hereditary cancer test. These allegations include the following:

200. ***First***, that Defendants' statements touting the GUIDED results as "positive" and as strong evidence of GeneSight's efficacy, including their statements characterizing the results of the Company's secondary and post-hoc analyses as "clinically meaningful and statistically significant," were directly contradicted by Myriad's own prespecified trial protocol and the FDA guidance to which the Company repeatedly stated it adhered, gives rise to a strong inference of scienter. As discussed above, the GUIDED clinical trial protocol specified that "[t]o account for multiple testing," Myriad was required to use "the Sidak correction" to adjust the threshold for statistical significance for each of its secondary endpoints. When these results are analyzed in accordance with Myriad's own prespecified rules for the GUIDED trial, there is ***no statistically significant difference*** favoring GeneSight on ***any*** of the endpoints Defendants vigorously and repeatedly touted during the Class Period. Indeed, FE 1, a Myriad scientist in the Medical Affairs department, confirmed that the GUIDED protocol codified the requirement that the p-values for the results on the study's non-primary endpoints be adjusted for multiplicity and that, if the adjustment were made as required, ***none*** of the results were actually statistically significant, as Myriad scientists discussed and agreed during the Class Period. Notably, the GUIDED protocol specifically lists Defendant Dechairo as the "Sponsor Clinical Monitor" for the trial, making clear that he was aware of, or, at a minimum, recklessly disregarded, the protocol's requirements. Moreover, Defendants repeatedly claimed, including in direct response to analyst questions, that GUIDED was conducted and reported in accordance with FDA guidance. That agency guidance, however, makes clear that "[p]ositive results on the secondary endpoints can be interpreted ***only*** if there is first a demonstration of a treatment effect on the primary endpoint family." (emphasis in original).

201. ***Second***, as discussed above, in late summer 2018, Defendants were privately warned by a panel of independent peer-reviewers at the highly prestigious *American Journal of Psychiatry* that their statements asserting that GUIDED provided strong evidence of GeneSight's efficacy were unsupported. As FE 1 explained, in late summer 2018, the *AJP* privately informed Myriad that the journal could not, and would not, publish the Company's claims that GUIDED had provided evidence of GeneSight's efficacy. FE 1 reported that, among other things, the *AJP's* peer reviewers pointed out that GeneSight had failed to achieve the study's primary endpoint, and that Myriad's heavy reliance on the supposedly "statistically significant" results on two of the study's many secondary endpoints was misplaced, since those results had not been adjusted for multiplicity, and, once adjusted, were, in truth, ***not*** statistically significant at all. FE 1 further stated that Myriad submitted a private response to *AJP's* peer reviewers, citing the Company's post-hoc analyses discussed above, but, later in the summer of 2018, the *AJP* once again explained to Myriad that its claims lacked scientific validity and rejected the Company's GUIDED manuscript a second time. Defendants not only failed to disclose these warnings, they affirmatively lied to investors about the reasons the *AJP* had rejected Myriad's GUIDED manuscript, concealing the experts' criticisms from the marketplace, even though Defendants knew investors were keenly focused on the formal publication of the GUIDED results as key to payor adoption. These warnings from prominent and independent experts, and Defendants fraudulent efforts to conceal them, further bolster the inference of scienter.

202. ***Third,*** Defendants knew, or recklessly disregarded, that the data available to the Company failed to provide sound, clinically meaningful evidence that GeneSight's ADHD and analgesic panels were effective in predicting patient drug response because this issue was discussed directly and repeatedly with senior Myriad executives, including Defendant Dechairo

and was widely reported and discussed inside the Company, even before the start of the Class Period. As discussed above, both FE 2 and FE 1 stated that the overwhelming consensus in Myriad's Medical Affairs department was that the data did not support inclusion of the ADHD and analgesic panels in the GeneSight offering. FE 1 referred to Myriad's claims of efficacy as "unsubstantiated" and "conjecture." Indeed, FE 2 reported that even the senior Myriad scientist who ran the group responsible for analyzing GeneSight data agreed that scientific support for the ADHD and analgesic panels was "weak." FE 2 reported that he, along with colleagues in Myriad's Medical Affairs and other Company employees, raised the lack of evidentiary support for the ADHD and analgesic panels directly with Defendant Dechairo on numerous occasions prior to the start of the Class Period, including at routine Company offsite meetings. Indeed, FE 2 reported that Dechairo stated that the Company would not perform analyses to obtain greater clarity on the efficacy of GeneSight's panels, including ADHD and analgesic, because the risk of a negative result would harm Myriad's ability to continue to market GeneSight. FE 1 likewise state that at a Company off-site meeting in July 2018, FE 1 and other Medical Affairs personnel expressed concerns to Myriad Neuroscience President Mark Verratti that the Company needed to validate the effectiveness of the ADHD and analgesic panels before marketing the panels to doctors and patients, and that Verratti responded by acknowledging that Myriad had not validated the panels, but, like Dechairo, stated that Myriad was not inclined to perform necessary testing. Accordingly, that Myriad's senior executives, including Dechairo, were not only warned by Myriad scientists that two of GeneSight's key panels lacked adequate empirical support, but refused to perform the analysis necessary to validate those panels, strongly supports an inference of scienter.

203. ***Fourth***, Myriad has ***admitted*** that throughout 2019, the Company overstated revenue attributable to its hereditary cancer test – the Company's largest and most significant revenue stream by far – by failing to account for ***known*** material declines in payor reimbursement. As discussed above, effective January 2019, the AMA eliminated the two "stacked" treatment codes referenced in many of Myriad's contracts with payors as the billing codes to be used to reimburse for the Company's hereditary cancer test. The Company sought to replace these obsolete "stacked" codes with the lucrative 81162 billing code, which billed at $2,200 per test, notwithstanding the proliferation of several far less expensive treatment codes for hereditary cancer testing, some billing at half the price. As a result of this negative pricing environment, Myriad faced significant investor pressure to demonstrate that its hereditary cancer test revenue remained strong and pricing remained favorable.

204. On Myriad's November 4, 2019 earnings call, Defendants admitted that despite knowing that CMS and the American Medical Association had issued far less expensive billing codes for hereditary cancer screening, Myriad accrued revenue reflecting that ***all*** of its payors would agree to pay for its test using the older, more lucrative 81162 code – the most expensive treatment code by far for hereditary cancer screening. Defendants further admitted that the Company did ***nothing*** to verify this assumption with thousands of payors. As also discussed above, Defendants' reporting of revenue without adequately accounting for, or even disclosing, these serious uncertainties violated GAAP, and Myriad was forced to correct their prior period financial reporting. At a minimum, it was severely reckless for Defendants to accrue revenue on the basis of unwarranted and unverified assumptions, without accounting for, or even disclosing, the serious uncertainties affecting that revenue, as required by GAAP.

205. Myriad further admitted on its November 4, 2019 earnings call that by no later than the fourth fiscal quarter of 2019 (the three months ended June 30, 2019), the Company observed a significant increase in the number of denied claims and "short" payments for its hereditary cancer testing, yet ***still*** failed to adjust its revenue accrual or report this negative trend, as, again, GAAP required. As Capone acknowledged, Myriad knew that payor reimbursement was not "consistent with our revenue accrual rate assumption." Again, Myriad's revenue reporting violated GAAP and the Company was forced to correct its prior period financial results. Accordingly, by their own admission, Defendants knew, but failed to disclose, material negative information concerning the Company's hereditary cancer test revenues.

206. Notably, Myriad's overstatement of revenue worked out remarkably well for the Company. As discussed above, but for the Company's overstatement of at least $7 million in hereditary cancer revenue in the third fiscal quarter of 2019 (the three months ended March 31, 2019), the Company would have reported an earnings loss for the quarter. The Company's misleading revenue accrual, however, allowed the Company to instead report a $7 million gain.

207. Heightening the inference of Capone and Riggsbee's scienter, both Defendants signed certifications in connection with the Company's SEC filings in late 2018 and early 2019 acknowledging a prior material weakness in Myriad's internal accounting controls over revenue accrual – the same process through which Myriad later overstated its hereditary cancer revenue. In connection with these signed certifications, Capone and Riggsbee specifically assured investors that both had personally ensured that Myriad's process for accruing revenue would "fully and timely take into account" changes in payor behavior at the very time Myriad was overstating its hereditary cancer revenue in violation of GAAP.

208. ***Fifth***, that Defendant Capone and Defendant Riggsbee dumped millions of dollars' worth of Myriad stock just before highly adverse news about GeneSight emerged further supports an inference of scienter. During the Class Period, as negative facts about GeneSight and the Company's hereditary cancer test revenue accumulated, Capone sold approximately 23% of his holdings, reaping total proceeds of nearly ***$13 million***. Capone's trading during the Class Period was highly unusual, departing from his historical trading patterns: during the eighteen months preceding the start of the eighteen-month Class Period (the "Control Period"), Capone did not sell a single share of Myriad stock. Additionally, Capone made no open market purchases of Myriad stock during the Class Period.

209. Likewise, Riggsbee sold approximately 10% of his holdings in Myriad stock during the Class Period, reaping $1,037,500 in proceeds, in a single highly suspicious transaction on August 1, 2019 discussed below. Like Capone, Riggsbee did not sell a single share of Myriad stock during the Control Period. Additionally, Riggsbee made no open market purchases of Myriad stock during the Class Period.

210. Importantly, as discussed above, Capone sold ***31%*** of his holdings (nearly half of all his intra-Class Period sales) and Riggsbee sold ***10%*** of his holdings (all of his intra-Class Period sales) in a ***single*** pre-planned transaction on August 1, 2019, reaping more than $6 million and $1 million in proceeds, respectively. Capone and Riggsbee made this sale just a single day after Myriad's stock had ***skyrocketed by 55%*** on the Company's announcement that United Health had decided to cover GeneSight, and ***just two weeks*** before Myriad stock ***plummeted by 42%*** as the Company finally disclosed highly adverse news about GeneSight – that Myriad had been forced to drop the test's ADHD and analgesic panels due to inadequate evidence of efficacy and that the FDA was scrutinizing GeneSight's psychotropic panel and had requested changes to the

test, facts both Capone and Riggsbee knew at the time of their August 1, 2019 sales. That Myriad conveniently rushed to broadcast highly positive news about GeneSight to the market ***just before*** Capone's and Riggsbee's pre-planned August 1, 2019 sales, while conveniently delaying disclosure of ***highly*** negative news about GeneSight that had long been in the Company's possession until ***after*** those pre-planned sales benefitted Capone and Riggsbee enormously. Had Capone's and Riggsbee's sales been executed after the Company's disclosure of negative GeneSight news just two weeks later, their proceeds would have been slashed almost in half.

211. ***Sixth***, that Defendants' misstatements concerned Myriad's two most material products and the GUIDED trial results – the single most important corporate event during the Class Period – further supports an inference of scienter, particularly as Myriad was a small company with little else to distract management or divide its attention. As alleged above, Defendants discussed GeneSight, a core product, on ***every*** investor call and during ***every*** conference attended during the Class Period, and hailed the test as a turning point for Myriad's business and the key to its future growth. For instance, Defendants stated that GeneSight was "one of [Myriad's] most important products," and would be "transformative to [the Company's] growth trajectory." Indeed, as discussed above, Defendants told investors that if GeneSight were fully reimbursed, Myriad would essentially double its 2017 Company-wide revenue. And, as Defendants repeatedly stated, the GUIDED trial was the most important step for Myriad in achieving expanded payor reimbursement and physician adoption. As Capone told investors, GUIDED was "the most important milestone for reimbursement . . . for GeneSight," and its "data will be instrumental in driving expanded coverage" for the test.

212. Likewise, as discussed above, GeneSight's hereditary cancer test was Myriad's largest revenue stream by far during the Class Period, single-handedly providing more than half

the entire Company's revenue. As such, Myriad's ability to maintain this important revenue stream was the focus of enormous investor attention. Indeed, as discussed above, analysts repeatedly raised questions ***specifically*** about Myriad's billing, coding, and reimbursement assumptions with respect to the Company's hereditary cancer testing. Moreover, as also discussed above, Capone and Riggsbee signed Certifications assuring investors that they were deeply focused on Myriad's revenue accrual process at the very time Myriad was overstating its hereditary cancer test revenue. Specifically, following the discovery of a material weakness in the Company's financial controls, both Capone and Riggsbee certified that they personally ensured that Myriad's process for accruing revenue would "fully and timely take into account" changes in payor behavior.

213. Analysts and investors agreed that GeneSight's growth, particularly vis a vis the GUIDED trial, and the stabilization of Myriad's hereditary cancer offering were the two single most important issues facing Myriad during the Class Period and the keys to the Company's profitability. As Morgan Stanley analysts stated in a February 7, 2018 report, "The narrative around MYGN includes optimism around the GeneSight reimbursement outlook . . . and price stabilization in hereditary cancer/myRisk that could support strong double-digit EPS growth beyond FY18."

214. Accordingly, that Defendants' misstatements concerned these critically important subjects, at a time when they were the focus of immense investor attention and concern, supports an inference of severe recklessness at a minimum.

215. ***Seventh***, that the lack of adequate empirical and clinical support for GeneSight's efficacy was widely discussed and well-known within Myriad, and was the subject of broad consensus among the Company's scientific personnel further supports an inference that these

adverse facts, which severely undermined Defendants' statements, could not have escaped management's notice. As discussed above, both FE 2 and FE 1 reported that the overwhelming consensus among Myriad scientists that there was not adequate empirical support for the efficacy of GeneSight's ADHD and analgesic panels, and that this issue was widely discussed internally and raised repeatedly with Myriad executives. Indeed, FE 2 could not think of anyone he spoke to about this that did not voice skepticism, including the senior Myriad scientist who ran the group responsible for analyzing GeneSight data. Likewise, FE 1 reported that Myriad's Medical Affairs scientists overwhelmingly agreed that the Company's attempt to hold up the results of post-hoc analyses and just two of the GUIDED study's numerous secondary endpoints as clinical evidence that the psychotropic panel was effective, notwithstanding the failure of the primary endpoint, was a "sham" and a "fishing expedition." In addition, FE 1 reported that Myriad received alarming feedback from clinicians that GeneSight was not effective and that, in a significant number of cases, following its recommendations had led to harmful clinical outcomes.

216. ***Eighth***, that the subjects of Defendants' misstatements were also the focus of intense regulatory scrutiny and concern during the Class Period further supports an inference that the true facts concerning these subjects could not reasonably have escaped Myriad management's notice. As alleged above, in October of 2018, the FDA issued a Safety Communication "warn[ing]" doctors and patients against "unapproved claims" by makers of pharmacogenetic tests, like GeneSight, that their product could be used to "predict patient response to specific medications." Following this Safety Communication, Myriad engaged in discussions with the FDA about the Company's marketing of GeneSight, specifically about removing GeneSight's ADHD and analgesic panels (which the Company did) and Myriad's claims about the GUIDED study. Given that the FDA's views on these issues would have had an outsized impact on the

Company's business and profitability, Myriad management could not reasonably have been unaware of the substance of these critical discussions.

217. ***Ninth***, the timing and circumstances surrounding the sudden and unexpected departure of Defendant Capone from Myriad and demotion of Defendant Dechairo further bolster the inference of their scienter. As discussed above, on February 6, 2020, Myriad announced that Capone and Myriad's Board "mutually agreed" that Capone – a 17-year veteran of Myriad, including 5 years as CEO – should resign "effective immediately," following the Company's shocking disclosures concerning the Company's withdrawal of two of GeneSight's key panels, the FDA's request that the Company make commercially devastating changes to the remainder of the test, and Myriad's over-accrual of hereditary cancer revenue. Moreover, Capone's departure followed his highly suspicious sale of Myriad stock on August 1, 2019, just after the Company pre-announced UnitedHealth coverage of GeneSight and just before it disclosed highly negative facts about GeneSight on August 14. There was no indication that Capone's departure was part of an orderly succession plan. To the contrary, even when the Company announced Capone's departure, it was still scrambling to find a replacement. Analysts characterized Capone's departure as "a surprise," "sudden," and "abrupt."

218. Similarly, as of February 10, 2020, Defendant Dechairo, whom Barclays analysts referred to as "the lead architect of Myriad's 'GeneSight Dossier' of clinical evidence," had been demoted from his position as Executive Officer of Myriad. Like Capone, Dechairo's demotion followed closely on the heels of Myriad's shocking disclosures about GeneSight's efficacy.

219. Notably, Capone's departure and Dechairo's demotion were preceded by several other suspiciously-timed high-profile departures. For instance, Myriad's Chief Medical Officer, Johnathan Lancaster, suddenly left Myriad in October 2019 after 7 years with the Company,

shortly after Myriad announced the withdrawal of GeneSight's ADHD and analgesic panels due to lack of supporting evidence and just prior to its announcement of further revenue losses driven by that withdrawal. Additionally, Myriad's long-time General Counsel, Richard Marsh, retired from the Company in July 2019, while the FDA was expressing serious concerns about GeneSight and pressing the Company to make commercially devastating changes to the test.

VI. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

220. During the Class Period, Defendants made a series of materially false and misleading statements to investors that fell into four categories: (A.) claims about the purported scientific support for Myriad's claims about the efficacy of its GeneSight ADHD and analgesic panel offerings; (B.) unsupported claims that the GeneSight psychotropic test was clinically proven, including by the findings of the GUIDED study, and related claims about the publication of the GUIDED study; (C.) statements describing Myriad's interactions with the FDA and the FDA's view of, and investigation into, the GeneSight test; and (D.) statements of Myriad's hereditary cancer test revenues.

A. Defendants' False and Misleading Statements and Omissions About the Efficacy of the GeneSight ADHD and Analgesic Panels

221. On August 9, 2017, Myriad filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended June 30, 2017 (the "2017 10-K"), which was signed by Defendants Capone and Riggsbee. The 2017 10-K falsely claimed that GeneSight, including its ADHD and chronic pain (analgesic) panels, "meets a significant unmet clinical need," and was "clinically proven to enhance medication selection":

> In the neuroscience market, our GeneSight test meets a significant unmet clinical need and is the leading product for psychotropic drug selection. It is used by healthcare providers to help patients who are affected by neuropsychiatric conditions including depression, anxiety, ADHD, bipolar disorder, schizophrenia, post-traumatic stress disorder (PTSD) and other behavioral health conditions, as

well as chronic pain. The test is clinically proven to enhance medication selection, helping healthcare providers get their patients on the right medication faster.

222. A year later, on August 24, 2018, Myriad filed its Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended June 30, 2018 (the "2018 10-K"), which was signed by Defendants Capone and Riggsbee. The 2018 10-K included the same language as set forth above from the 2017 10-K.

223. The above-quoted statements in the 2017 and 2018 10-Ks were materially false and misleading when made. Rather than GeneSight "meet[ing] a significant unmet clinical need" or being "clinically proven to enhance medication selection" in patients with "ADHD" or "chronic pain," Myriad lacked clinical evidence to support GeneSight's ability to meet a clinical need, or enhance medication selection, in patients with ADHD or chronic pain. Specifically, by the time that Myriad filed the 2017 and 2018 10-Ks, it was the internal consensus at Myriad that there was no clinical support for the efficacy of GeneSight's ADHD and chronic pain panels.

224. In addition, on Myriad's GeneSight website, throughout the Class Period, Defendants advertised the GeneSight ADHD and analgesic panels as part of the "clinically proven" GeneSight product offering. Specifically:

- As of August 23, 2017 and May 15, 2019, for the ADHD panel, the GeneSight website claimed that "If you or your child have Attention-Deficit / Hyperactivity Disorder, this genetic test can help quickly and accurately determine which drugs will work best with your (or your child's) genes";
- As of August 23, 2017 and February 22, 2019, for the chronic pain panel, the GeneSight website claimed that "For those experiencing acute or chronic pain, this genetic test analyzes how your genes affect your body's response to FDA-approved opioids, NSAIDs and muscle relaxants to accurately determine which medications are optimal";
- As of July 26, 2018 and February 22, 2019, the GeneSight website claimed that "[GeneSight] can help quickly and accurately determine which ADHD medications will work best with your (or your child's) genes";
- As of July 26, 2018, the GeneSight website claimed that "[t]he GeneSight ADHD

genetic test can reduce [the anxiety of taking ADHD drugs] by helping doctors to identify and avoid ADHD medications more likely to cause side effects based on your genetics";

- As of July 26, 2018, the GeneSight website claimed that "The GeneSight Analgesic genetic test analyzes how your genes affect your body's response to FDA-approved opioids, NSAIDs and muscle relaxants commonly prescribed to treat acute or chronic pain, opioid dependency and osteoarthritis (OA)" and "Results can help your healthcare provider select the medications that best complement your genes and help you feel well again";

- As of May 15, 2019, the GeneSight website claimed that "this genetic test analyzes how your genes affect your body's response to FDA-approved opioids, NSAIDs and muscle relaxants to accurately determine which medications are optimal"; and

- As of February 22, 2019, the GeneSight website claimed that patients were "2x more likely to respond to selected meds after taking the GeneSight test."

225. The above-quoted statements from the GeneSight website were materially false and misleading when made because Myriad lacked clinical evidence to support GeneSight's ability to "quickly and accurately determine" which ADHD drugs will work best with a patient's genes; "accurately determine which [pain] medications are optimal" for a given patient; "help[] doctors to identify and avoid ADHD medications more likely to cause side effects based on [a patient's] genetics"; "analyz[e] how your genes affect your body's response to [medications] prescribed to treat acute or chronic pain"; or "help your healthcare provider select the medications that best complement your genes and help you feel well again." In truth, as Defendants were well-aware, there was no meaningful evidence supporting GeneSight's claimed ability to predict patient response to particular ADHD or pain relief drugs. Indeed, as the Former Employees explained, the overwhelming consensus in Myriad's Medical Affairs department was that the data did not support inclusion of the ADHD and analgesic panels in the GeneSight offering, and that Myriad's claims to the contrary were "unsubstantiated" and "conjecture."

226. On August 1, 2019, Myriad filed a Form 8-K announcing that "UnitedHealthcare has issued a positive coverage decision for pharmacogenetic testing for multi-gene panels

including the company's GeneSight Psychotropic test. The coverage is for patients that have a diagnosis of major depressive disorder or anxiety and have failed at least one prior medication to treat their condition."

227. The foregoing statement on Myriad's August 1, 2019 Form 8-K was materially false and misleading when made. It was misleading for Defendants to tout GeneSight and its commercial prospects, while failing to disclose that (1) Myriad had removed the ADHD and analgesic GeneSight panels; and (2) the FDA had privately expressed serious concern to Myriad about GeneSight and had requested the Company make commercially devastating changes to the test.

B. Defendants' False and Misleading Statements and Omissions Concerning the Purportedly Positive Results of Myriad's GeneSight GUIDED study

1. First Quarter 2018

228. In a November 2, 2017 press release, Myriad purported to announce the "positive results" from the GUIDED study, stating:

> The study was designed to evaluate three key endpoints relative to HAMD-17 scores: remission (HAMD-17 score ≤7), response (HAMD-17 reduction >50%), and symptom reduction. Patients receiving the GeneSight test achieved a clinically meaningful and statistically significant improvement in both remission rates ($p<0.01$) and response rates ($p=0.01$) at eight weeks compared to the treatment-as-usual group. In addition, patients who received the GeneSight test had a greater reduction in HAMD-17 scores after eight weeks, compared to the treatment-as-usual group, with the difference approaching statistical significance ($p=0.1$). Lastly, the improvement in remission, response, and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period.

229. Myriad's press release was materially false and misleading. *First*, contrary to Defendants' claims, GUIDED was ***not*** "designed to evaluate three key endpoints." Rather, GUIDED had a single primary endpoint, symptom reduction, which GeneSight failed to achieve. Far from being "key endpoints," Defendants' cherry-picked "response" and "remission" results

were only two of the study's 65 ***secondary*** endpoints. *Second*, contrary to Defendants' statements that GeneSight patients in the study achieved "clinically meaningful and statistically significant improvement" in response and remission, FDA guidance and standard clinical trial practice make clear that these secondary endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family." Thus, in reality, the "response" and "remission" results that Defendants enthusiastically touted provided no empirically sound support for GeneSight's efficacy. *Third*, Defendants' claim that GeneSight patients in the GUIDED trial achieved "statistically significant improvement" in response and remission was additionally false and misleading because, in truth, when these results are analyzed in accordance with Myriad's own prespecified rules for the GUIDED trial, there is no statistically significant difference in response and remission rates between GeneSight and "treatment as usual" patients.

230. Myriad's November 2, 2017 press release further quoted John Greden, the study's paid author, as stating, "From a clinician's perspective, better but not well is not good enough and significant improvements in response and remission are always the most-desired endpoints." Likewise, Executive Vice President of Clinical Development Bryan Dechairo stated in the press release, "Improving remission and response rates are key treatment goals of clinicians because they directly improve patients' lives and reduce healthcare costs. These endpoints also align with payer goals, and we look forward to having those discussions in the coming months."

231. These statements by Myriad and Dechairo were materially false and misleading when made. *First*, FDA guidance and standard clinical trial practice make clear that GUIDED's response and remissions endpoints could not even be analyzed because there was no "demonstration of a treatment effect on the primary endpoint family." Thus, in reality, the "response" and "remission" results that Defendants enthusiastically touted provided no

empirically sound support for GeneSight's efficacy. *Second*, when the response and remission results Myriad touted are analyzed in accordance with the Company's own prespecified rules for the GUIDED trial, there is no statistically significant difference in response and remission rates between GeneSight and treatment as usual patients. *Third*, as Myriad scientists internally recognized, response and remission lacked the clinical value Defendants misleadingly ascribed to them.

232. On November 7, 2017, on Myriad's Q1 2018 earnings call, Defendant Capone discussed the purportedly positive results of the highly-anticipated GUIDED study:

> The primary goal was to assess the HAM-D17 scores at 4 and 8 weeks compared to baseline and to calculate 3 endpoints: percent of patients in remission; percent of patients that are responders; and the percent symptom reduction . . . . We believe the data from this study ***clearly demonstrates the clinical utility of the GeneSight test***. We saw an improvement in depressive symptoms for the entire cohort, which was approaching statistical significance. More importantly, in ***the 2 most critical endpoints for physicians and payers, response and remission, we achieved a high degree of statistical significance***. Lastly, the improvement in remission, response and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period.
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> ***GeneSight achieved statistical significance for the 2 gold standard clinical outcomes of response and remission*** in the 1,200-patient prospective randomized controlled trial. This is a landmark event in our company's history, and we believe will pave the way for broader GeneSight adoption and payer coverage.
>
> * * *
>
> For GeneSight to achieve ***clinically meaningful and statistically significant improvements in the remission and response endpoints*** certainly exceeded our expectations.
>
> * * *
>
> In summary, with GeneSight now having amassed an extensive dossier for treatment-resistant depressed patients, and having ***demonstrated success*** in [the GUIDED] prospective clinical study, we continue to believe this product can materially transform our financial performance in the future.

* * *

> After the 12-week endpoint, the 8-week end point was the ***primary endpoint for the evaluation of those 3 remission, response and symptom reduction***.
>
> * * *
>
> The reason that the clinical trial milestone was tied to symptoms is that in historical antidepressant studies, symptom reduction as a continuous variable is generally the easiest end point to hit. That was certainly the perception in this case, and so we agree that we would accept that as the singular milestone payment for this particular agreement was that -- on that symptom reduction . . . But we accepted that as the sole endpoint because in a traditional antidepressant study, it is the easiest endpoint to meet. I think what is important to note is it was not the endpoint because it was the most important. It was really because as we negotiated a deal, it was perceived as the easiest, and I think that's an important distinction.

233. The foregoing statements by Capone from Myriad's November 7, 2017 investor call were materially false and misleading when made because: (i) neither response nor remission was the "primary goal," "primary endpoint," or "gold standard clinical outcomes" of the GUIDED study but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from "clearly demonstrate[ing] the clinical utility of the GeneSight test" or GeneSight's "success," and far from GeneSight achieving "clinically meaningful and statistically significant improvements" in response and remission, FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iv) the GUIDED study did not achieve statistical significance, and was not "clinically meaningful" on the secondary endpoints of response and remission, and Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (v) contrary to Defendants' statements attempting to downplay the clinical

significance of GUIDED's primary endpoint (and GeneSight's failure to achieve it), neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and, as Myriad scientists internally recognized, lacked the clinical value Defendants misleadingly ascribed to them.

234. On November 16, 2017, Myriad attended the Jefferies Healthcare Conference and, in a slide presentation to investors, reiterated the "top-line" results from the GUIDED study. In the presentation, Myriad touted GeneSight's supposedly "highly statistically significant" remission results, and stated the endpoint was "very important" to clinicians and payors. Similarly, Myriad described the response endpoint as "difficult to achieve," yet the GUIDED study result was "highly statistically significant" with a p-value of 0.01, and again, "very important" to clinicians and payors. In fact, the same slide stated that the GUIDED study resulted in "[s]tatistically significant improvement in gold-standard outcomes of response and remission at eight weeks. The relevant chart from the presentation is included below:

Study endpoint	What it Means	Study Result	Importance to Clinicians and Payers
Remission hardest to achieve	Patient no longer depressed	Highly statistically significant ($p<0.01$)	Very important
Response difficult to achieve	Patient feels a lot better	Highly statistically significant ($p=0.01$)	Very important
Symptom Improvement most likely to achieve	Patient feels somewhat better	Approaching statistical significance ($p=0.1$)	Meaningful

235. The foregoing statements by Myriad in the November 16, 2017 Company presentation were materially false and misleading when made because: (i) Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) contrary to Defendants' statements attempting to downplay the clinical significance of GUIDED's primary endpoint (and

GeneSight's failure to achieve it), and as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; (iii) far from achieving "highly statistically significant" improvements in response and remission, FDA guidance and standard clinical trial practice make clear that these endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; and (iv) the GUIDED study did not achieve "highly statistically significant" improvements on the secondary endpoints of response and remission, and Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance.

236. On January 9, 2018, at the JP Morgan Healthcare Conference, Defendant Capone continued portraying the GUIDED study as scientifically validating GeneSight:

> The endpoint was based on HAM-D17 scores, which is a 17-item questionnaire that's administered to patients and certified by central raters. ***And there were 3 calculations based on that singular endpoint. Those being response, remission and symptom improvements.***
>
> * * *
>
> The results of this study exceeded our expectation. ***They were outstanding. GeneSight showed highly statistically significant results in the endpoints that matter most***. In fact, the ***most important endpoint is remission*** . . . . And GeneSight was ***highly statistically significant*** when compared to treatment as usual.
>
> GeneSight also was ***highly statistically significant*** at the response endpoint. . . . Also equally important is remission, response and symptoms improvements were durable. And in fact, continued to improve throughout the entire 24-week time frame.

237. The foregoing statements by Capone during the January 9, 2018 healthcare conference were materially false and misleading when made because: (i) neither response nor remission were part of a "singular endpoint" of the GUIDED study but Defendants misled

investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary; (ii) far from being "outstanding" and "most important," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission, and Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

2. Second Quarter 2018

238. On February 6, 2018, on the Myriad 2Q 2018 earnings call, Defendant Capone continued to tout the purported success of the GUIDED study's "top-level" data:

> With GeneSight, we released top line data, demonstrating the ability of the test to improve ***the gold standard clinical outcomes of remission and response in the largest pharmacogenetics study ever conducted***.
>
> * * *
>
> We remain excited about the presentation and publication of the full data set from our 1,200-patient randomized controlled trial by the end of this fiscal year. Early feedback and the top line data from physicians has been exceptional, with doctors clearly impressed at the ***statistically significant improvements in the gold standard clinical outcomes of remission and response***, given the unprecedented comparison to an actively managed optimized drug control arm.

239. The foregoing statements by Capone from Myriad's February 6, 2018 investor call were materially false and misleading when made because: (i) neither response nor remission was the primary endpoint or "gold standard clinical outcomes" of the GUIDED study but Defendants

misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from demonstrating "statistically significant improvements in the gold standard clinical outcomes of remission and response" for GeneSight, FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

3. Third Quarter 2018

240. On May 8, 2018, at a Deutsche Bank investor conference held after Myriad presented its GUIDED study results in abbreviated poster format at the APA annual conference, Defendant Capone continued to claim that the GUIDED study was supposedly definitive proof of the efficacy of GeneSight, failing to even discuss the study's primary endpoint:

> Most importantly, as Dan mentioned, we actually announced some critical data at the APA Convention down in New York yesterday. I think it's important because for GeneSight, if that product was actually fully reimbursed for the volumes we are running today, it would be over $0.5 billion of revenue per year. And the key data to get us to that broad scale reimbursement was the data we announced yesterday. Very quickly ***top line results***: ***50% improvement in remission, 30% improvement in response for treatment-resistant depressed patients. So this was really outstanding data***, largest-ever study in pharmacogenomics, and we think will pave the way.

241. And, in response to an analyst question concerning the "time line" for general practitioner adoption of GeneSight, Capone claimed:

> Sure. Obviously, the data was exceptional. We're very pleased with it on many fronts. I think ***the most important thing we were able to demonstrate is significant improvements in remission and response, which are the endpoints that matter most to clinicians, to patients and to payers, and statistically significant results there***. We showed the results were durable. In fact, they continued to improve throughout the 6-month time frame of the study. In addition to that, we showed that for patients that were [sic] entered this study on incongruent or red medications, those that were not congruent with their genetic profile, that ***switching those patients to a medication that was congruent to their genetic profile had dramatic improvement in their outcomes***. 53% improvement in remission, 79% improvement – or 71% improvement in response and 59% improvement in symptoms.

242. The foregoing statements by Capone at the May 8, 2018 Deutsche Bank investor conference were materially false and misleading when made because: (i) neither response nor remission was the primary endpoint or "top line results" of the GUIDED study but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from being "outstanding" or "exceptional," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (v) contrary to Defendants' claims, the results of its post-hoc "congruent/incongruent" subgroup analysis were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

243. On May 8, 2018, Myriad also held its third quarter (the three months ended March 31, 2018) earnings call. On that call, Defendant Capone continued to tout the results from the GUIDED study:

> I would like to begin the discussion with GeneSight results starting with ***the 3 clinical outcomes of remission, response and symptom improvement over the 8-week blinded period of the study***. Importantly, the GeneSight-guided arm performed better in all 3 areas, showing a highly statistically significant improvement in remission and response rates and an improvement in symptoms that was trending towards statistical significance. Impressively, GeneSight led to a 50% improvement in remission and a 30% improvement in response rate relative to the treatment-as-usual arm. This is the first time to our knowledge that a technology has ***demonstrated a statistically significant improvement in outcomes*** relative to an active drug arm for depression.
>
> Our positive top line results from the randomized clinical trial continues to result in increased interest and utilization . . . With GeneSight, we presented the landmark results from the randomized controlled trial yesterday at the American Psychiatric Association meeting. The data showed the ability of GeneSight to ***significantly improve outcomes in treatment-resistant depressed patients*** when compared to a physician-optimized drug control arm in the largest prospective pharmacogenomics study in history.
>
> * * *
>
> The study ***evaluated 3 key endpoints*** related to HAM-D17 scores, including remission, which is defined clinically as a patient decreasing their HAM-D17 score to less than or equal to 7; response, which is defined as the patient having a reduction of greater than 50% in their HAM-D17 score; and symptom improvement, which is defined as the percentage change in a patient's HAM-D17 score.

244. On that same May 8, 2018 third quarter earnings call, Defendant Dechairo further proclaimed the results of the GUIDED study through an improper post-hoc analysis of the GUIDED data:

> I would like to begin the discussion with GeneSight results starting with ***the 3 clinical outcomes of remission, response and symptom improvement over the 8-week blinded period of the study***. Importantly, the GeneSight-guided arm performed better in all 3 areas, showing a ***highly statistically significant improvement in remission and response rates*** and an improvement in symptoms that was trending towards statistical significance. Impressively, GeneSight led to a

50% improvement in remission and a 30% improvement in response rate relative to the treatment-as-usual arm. This is the first time to our knowledge that a technology has demonstrated a statistically significant improvement in outcomes relative to an active drug arm for depression.

The explanation for symptom improvement trending towards statistical significance can be seen on this slide. The chart on the left shows the relative symptom improvement at the 8-week time point in the GeneSight arm compared to the treatment-as-usual arm based upon the worst color medication the patient was taking when entering the study. The results are exactly what you would expect. For patients entering the study on a green medication, the GeneSight test provides little benefit because the medications remain unchanged in both arms. For patients entering on a yellow medication, there are improved outcomes in the GeneSight arm because the test identified the direction of dose adjustment needed to match the patient's genetic profile. The most significant benefit is for patients entering on red medication because the GeneSight report will identify the genetic mismatch and recommend other more appropriate medication. ***In the study, patients entering on red medications in the GeneSight arm saw a 33% relative improvement in symptoms compared to those entering on red medications in the TAU arm when evaluated at the 8-week time point***. However, only 21% of patients entered the study on red medication. As a result, when the entire cohort is analyzed, the significant symptom improvement for patients entering on red medications is diluted by the 79% of patients that entered the study on green or yellow medications.

Now I would like to look at a deeper analysis for patients who are on genetically incongruent medications at baseline . . . . Importantly, from a clinical utility perspective, patients in the GeneSight-guided arm saw a 57% decrease in incongruence rate, while the treatment-as-usual arm experienced a 9% increase in incongruence rate. ***This clearly demonstrates that the trial-and-error methodology did not lead to higher rates of genetic congruence over time. Only when guided by GeneSight were physicians able to increase congruence***.

The study data showed that those patients who entered the study on a genetically incongruent medication ***performed significantly better when switching to a congruent medication***.

You can see the durability of these results across the open-label period of the study. Patients continued to see improvements in all 3 major clinical endpoints with remission rates at 24 weeks of 30%, response rates of 45% and symptom improvement of 42%.

* * *

The study showed the ability of GeneSight to improve remission and response rates with a durable result that improved over time, and it establishes a new

> ***standard of care to identify patients on incongruent medications and switch them to congruent medications***. We believe this level 1 evidence will provide a significant catalyst to broaden payer coverage when combined with the current and future health economic publications.

245. Further, in response to a question from an analyst concerning how physicians reacted to the data from the GUIDED study presented at the 2018 American Psychological Association's annual conference, Defendant Capone stated:

> It was a very large, prospective, double-blind study that showed both statistically significant results in 8 weeks and showed a durability of response.

Similarly, Defendant Dechairo stated:

> Because overall, with our 50% improvement in remission and 30% improvement in response in the total population, that's great clinical utility. But people want to understand where does that utility come from, and it comes from the GeneSight test. And so ***by being able to show them that 21% of patients who were incongruent basically on a genetically inappropriate medication coming in, who switched off of it, have the largest improvements in symptom improvement, response and remission and drove the overall benefits in the total population, that proves the clinical validity of the test, that it's the genetics that drives it***.

246. The foregoing statements by Capone and Dechairo on May 8, 2018 were materially false and misleading when made because: (i) neither response nor remission was the primary endpoint or main "3 clinical outcomes," "3 key endpoints," or "topline results" of the GUIDED study but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from "show[ing] the ability of GeneSight to significantly improve outcomes in treatment-resistant depressed patients," "perform[ing] better in all 3 areas," demonstrating "great clinical utility," and "establish[ing] a new standard of care to identify patients on incongruent medications and switch them to congruent medications," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did

not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (iv) contrary to Defendants' claims that Myriad's post-hoc analyses "prov[e] the clinical validity of" GeneSight or explain away the product's failure to achieve GUIDED's primary endpoint, the results of its post-hoc analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

247. On May 16, 2018, at the annual Bank of America Merrill Lynch Healthcare Conference, in response to an analyst asking for a "30-second overview of the GeneSight data," Capone touted the purported statistical significance of the response and remission endpoints:

> So the data for GeneSight was, in many ways, unprecedented. . . .
>
> What we showed at the 8-week time point, which is the standard FDA approval time point, we ***showed that there was a 50% improvement in remission, a 30% improvement in response and a 12% improvement in symptoms at that 8-week time point for patients that were in the GeneSight arm***.
>
> ***The first 2 of those endpoints were statistically significant***, and the symptom improvement endpoint was approaching significance. We also -- the other key part of the study was to look at how durable the GeneSight results were, and so we looked at that data all the way out to 6 months. And we saw that remission, response and symptom improvements continued all the way through the study, continued to improve. And in fact, by the time we got to the 6-month time point, we had 30% remission rates for those patients in the GeneSight arm.
>
> The last data we showed that was important was a subset analysis to look at the group of patients that entered the study on what we call red medications. Those are medications that are misaligned with the genetic profile of the patient. And we looked specifically at how those patients did when they were switched over to medications that were aligned to their genetic profile compared to patients that

> entered on a red medication but did not switch off of those red medications during that study.
>
> At the 8-week time point, we saw dramatic differences between those 2, 153% improvement in remissions, 71% improvement in response and a 59% improvement in symptoms, all of which were statistically significant. And so ***en masse, the data showed very clearly that treating patients with GeneSight would enable better outcomes than treatment-as-usual arm that was optimized by psychiatrists***.

248. The foregoing statements by Capone on May 16, 2018 were materially false and misleading when made because: (i) contrary to Defendants' statements, GeneSight did not show "improvement" in response, remission, or symptom improvement because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (ii) far from "show[ing] very clearly that treating patients with GeneSight would enable better outcomes than treatment-as-usual," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (v) contrary to Defendants' claims, the results of its post-hoc analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

249. At the June 12, 2018 Goldman Sachs 39th Annual Global Healthcare Conference, Capone continued to tout the results of the GUIDED study, this time promising that its results were key to additional payor reimbursement: "So the substantial opportunity for GeneSight as

we obtain additional reimbursement, the keys to getting reimbursement are the publication of the prospective study that we announced full data on at the APA meeting. ***That data was excellent. It showed a 50% increase in remission and a 30% increase in response for patients whose care was guided by GeneSight***."

250. The foregoing statements by Capone on June 12, 2018 were materially false and misleading when made because: (i) neither response nor remission was the primary endpoint of the GUIDED study but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from being "excellent," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

4. Fourth Quarter 2018

251. On August 21, 2018, during Myriad's Q4 2018 earnings call, Defendant Capone not only described the "***positive results***" of GUIDED as statistically significant, but also claimed that GeneSight was "the first pharmacogenomics technology to demonstrate ***statistically significant changes in response and remission rates*** versus an active drug arm." Further, Defendant Capone stated that the publication of the GUIDED data would put Myriad in a "strong position to receive additional coverage decisions" and that "***the GUIDED [] stud[y] [was] in the***

later stages of review" for publication.

252. The foregoing statements by Capone on August 21, 2018 were materially false and misleading when made because: (i) far from being "positive," FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (ii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iii) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (iv) GUIDED was ***not*** in the "later stages of review" but rather, the *AJP* had rejected Myriad's manuscript because the Company's claims were unsound and that, far from being in the "later stages of review," the study was only in its second day of review at the *Journal of Psychiatric Research* after its rejection from the far more prestigious *AJP*.

253. On August 24, 2018, Myriad filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended June 30, 2018 (i.e., the "2018 10-K"), which was signed by Defendants Capone and Riggsbee. The 2018 10-K claimed that "[m]ultiple clinical studies have shown that when clinicians used GeneSight to help guide treatment decisions, patients were more likely to respond to the selected medication compared to standard of care." The 2018 10-K also highlighted "results from the GeneSight GUIDED randomized controlled trial at the American Psychiatric Association annual meeting,"

and asserted that "[t]he landmark study ***showed that patients receiving GeneSight had significantly better outcomes with a 50 percent increase in remission rates and a 30 percent increase in response rates relative to those who received standard of care therapy***."

254. The foregoing statements in Myriad's 2018 10-K were materially false and misleading when made because: (i) contrary to Defendants' statements, GeneSight did not show that "patients receiving GeneSight had significantly better outcomes" than standard of care therapy because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (ii) FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

5. First Quarter 2019

255. On September 13, 2018, at the Morgan Stanley Healthcare conference, in response to a question from an analyst about the significance of the publication of the GUIDED study and reimbursement progress with payors, Defendant Capone claimed:

> I think the data was really unprecedented in many ways, ***showing remission and response data compared to an active drug arm***. It's something that has rarely occurred. . . .
>
> * * *
>
> I think one of the easy surrogate endpoints in this case is the number of patients that

> are on red medications. So that's really important data, that hopefully all the investors have looked at for the GeneSight study, that shows what happens when you switch a patient off of red medications compared to those patients that stay on red medications. And ***the results were striking and highly statistically significant across all endpoints***. And so that becomes a very easy thing to measure, and ***is very good surrogate for how many patients are on red medications and those that are not up. And we can help payers characterize that for their members and provide that type of evidence***.

256. The foregoing statements by Capone on September 13, 2018 were materially false and misleading when made because: (i) FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (ii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iii) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (iv) far from being "striking and highly statistically significant across all endpoints," the results of Myriad's post-hoc subgroup analysis were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

257. On the November 6, 2018 Q1 2019 Myriad earnings call, Defendant Capone falsely and misleadingly told investors that the sole reason that GUIDED was not accepted to an undisclosed medical journal was because the journal had requested Myriad's disclosure of GeneSight's proprietary algorithm to the journal:

> For GeneSight, we are anticipating acceptance of the landmark GUIDED publication by the end of the fiscal second quarter. While we had anticipated this publication earlier, it was delayed because the manuscript was withdrawn and submitted to a second journal. At the end of the review process, the first journal

> notified the company that as a condition of publication the proprietary GeneSight algorithm would need to be disclosed. Solely based upon the desire to protect our intellectual property, the manuscript was withdrawn and submitted to another journal, and we are anticipating acceptance in the second quarter.

258. Capone's statement on the November 6, 2018 conference call that Myriad had voluntarily withdrawn the GUIDED study manuscript "solely" because Myriad wanted to protect its intellectual property from disclosure was materially false and misleading because the journal in question had instead rejected the GUIDED study manuscript because, among other things, Defendants' assertions about the GUIDED data were unsupported and unsound.

259. Additionally on that call, Capone further touted Myriad's supposedly favorable post-hoc analyses of the GUIDED data as providing strong support for GeneSight's efficacy:

> An additional analysis compared 57% of patients that switched to the 43% of patients that did not. And it was shown ***that patients switching from red medications experienced a 153% increase in remission, a 71% increase in the response and a 59% improvement in symptoms, and all of these results were highly statistically significant***. In fact, modeling has shown that had the 43% of patients also switched from red medications, all endpoints improved and were statistically significant.

260. The foregoing statements by Capone on November 6, 2018 were materially false and misleading when made because far from being "highly statistically significant," the results of Myriad's post-hoc subgroup analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

6. Second Quarter 2019

261. On January 4, 2019, Myriad's GUIDED medical journal article, authored by Defendant Dechairo and others, was published in the *Journal of Psychiatric Research*. The article stated:

- "[I]mprovements in response (26.0% versus 19.9%, p = 0.013) and remission (15.3% versus 10.1%, p = 0.007) were statistically significant";
- "Patients taking incongruent medications prior to baseline who switched to

congruent medications by week 8 experienced greater symptom improvement (33.5% versus 21.1%, p = 0.002), response (28.5% versus 16.7%, p = 0.036), and remission (21.5% versus 8.5%), p = 0.007) compared to those remaining incongruent";

- "Pharmacogenomic testing . . . did significantly improve response and remission rates for difficult-to-treat depression patients over standard of care";
- "Differences in the key secondary outcomes of response and remission were positive and significant";
- "The analysis of patients on incongruent medications at baseline showed that outcomes were significantly improved among those who switched to a congruent medication by week 8";
- "When only patients taking genetically incongruent medications at baseline were assessed, symptom improvement was significantly better among patients who switched to congruent medications at week 8 compared to those who remained on incongruent medications (Δ = 12.4%, p = 0.002)";
- "[T]he modest but important improvements in response and remission for patients in the guided-care arm are clinically meaningful";
- "[T]his randomized controlled trial found that weighted and combined multi-gene pharmacogenomic testing significantly increased clinical response and remission rates for patients with MDD [major depressive disorder] in the guided-care arm versus TAU [treatment as usual]. Pharmacogenomic testing predominantly helped those patients whose treatment resistance may have been related to genetically incongruent medications. . . . These results from the GUIDED trial indicate that pharmacogenomic testing is effective in improving response and remission rates among those with prior treatment resistance, particularly for patients who are treated with medications that are incongruent with their genetic profile"; and
- "Continuous changes in HAM-D17 score from baseline to week 8 were assessed to evaluate why the continuous endpoint of symptom improvement did not reach statistical significance while the categorical endpoints (response, remission) were significant. This revealed that the distribution of continuous HAM-D17 score improvement from baseline to week 8 was shifted towards extreme improvement ($\geq$50% decrease in HAM-D17; definition of response) in the guided care arm and towards modest improvement in TAU (Supplemental Fig. 2). As a result, the mean HAM-D17 improvement was similar for both study arms (Δ2.8%, p = 0.107) while the proportion of patients with extreme improvement in the guided-care arm drove a significant difference in the rate of response and remission."

262. The foregoing statements by Defendants Myriad and Dechairo were materially false and misleading when made because: (i) contrary to Defendants' statements, GeneSight did

not show "improvements" in response, remission, or symptom improvement because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (ii) far from demonstrating that GeneSight "significantly improve[d] response and remission rates for difficult-to-treat depression patients over standard of care" and contrary to the statements that these results were "clinically meaningful," FDA guidance and standard clinical trial practice make clear that GUIDED's cherry-picked response and remission endpoints (two of the study's 65 endpoints) could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; (v) the results of Myriad's post-hoc "congruent/incongruent" subgroup analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized and (vi) As Former Employees explained, despite skepticism expressed internally by Myriad scientists that "that the distribution of continuous HAM-D17 score improvement from baseline to week 8 was shifted towards extreme improvement" in any statistically significant sense, the Company failed to perform any analysis to verify the claim's accuracy.

263. On January 4, 2019, following the Barclays analyst call with Dr. Nemeroff discussed above, Myriad held a conference call with investors concerning the GUIDED study. On that call, Capone reiterated the purported strength of the GUIDED study data, falsely claiming

GeneSight showed "improvement" on every endpoint and statistically significant results achieved in response, remission, and other cherry-picked secondary endpoints:

> The next slide shows the results for the 3 outcomes of remission, response and symptom improvement over the 8-week blinded period of the study. ***Importantly, the GeneSight GUIDED arm performed better in all 3 endpoints, showing a highly statistically significant improvement in remission and response rates and an improvement of symptoms that was approaching statistical significance***.
>
> Overall, GeneSight led to a 50% improvement in remission rates, a 30% improvement in response rates, and an 11% improvement in symptoms relative to the treatment-as-usual arm. ***This is the first time, to our knowledge, that a technology has demonstrated a statistically significant improvement in overall outcomes relative to an optimized active drug arm for depression***.
>
> The next slide shows the durability of results. Importantly, all 3 key endpoints of remission rates, response rates and symptom improvement continued to improve over the 24-week time frame, and remission rates more than doubled between week 8 and week 24 in the GeneSight GUIDED arm. This finding has been well received by payers that wanted assurance that the GeneSight benefits are enduring.
>
> * * *
>
> Additionally, in the endpoints used by the FDA and payers, 4 out of the 6 achieved statistical significance, and the other 2 approached significance of p values of 0.07. Also, every endpoint demonstrated statistical significance in at least one of the depression instruments, including symptom improvement. . . . The robustness and breadth of these results provide even further evidence that GeneSight GUIDED therapy provides superior outcomes for treatment-resistant depressed patients

264. The foregoing statements by Capone on January 4, 2019 were materially false and misleading when made because: (i) Capone's reference to "all 3 endpoints" misled investors by touting two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) contrary to Defendants' statements, GeneSight did not show "improvement" in response, remission, or symptom improvement because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (iii) far from achieving "highly statistically significant improvement in remission and response rates" in response and remission and "statistical significance" in additional cherry-picked secondary endpoints, FDA

guidance and standard clinical trial practice make clear that these endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iv) the GUIDED study did not achieve statistical significance, and was not clinically meaningful on ***any*** of its selectively reported secondary endpoints, including response and remission, and Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that these secondary endpoints, including response and remission, in fact lacked statistical significance; and (v) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

265. On that same January 4, 2019 call, Defendants Dechairo and Capone continued to laud the purported results of the GUIDED study, highlighting the results of yet another post-hoc analysis of the GUIDED data as strongly demonstrating the product's efficacy:

> **Dechairo:** Additional analyses were performed on the 21% of patients that entered the study on red, genetically incongruent medications, who should benefit the most from GeneSight testing. Note that in the treatment-as-usual arm, without the benefit of the GeneSight report, the percent of patients on red medications actually increased over the 8-week study period demonstrating that physicians were unable to improve congruence using the trial-and-error approach. However, in the GeneSight arm, 57% of patients were switched from red medications, significantly improving congruence.
>
> There were 3 factors that contributed to the 43% of patients who remained on red medications in the GeneSight arm: first, switching was not required in the protocol; second, physicians were naive to GeneSight; and third, patients were blinded to the fact that they were taking red medications.
>
> Because some patients remained on red medications and some were switched, we were able to do a separate analysis comparing these 2 patient groups. ***When comparing these 2 patient groups, the patients that switched from red medications experienced remission rates that were 153% higher, response rates that were 71% higher and symptom improvement that was 59% higher. All of these results were highly statistically significant***.

* * *

Dechairo: An additional analysis was performed based upon other observations noted during the manuscript review process. The peer protocol analysis was diluted by the 30% of patients that entered the study on green medications only and who were not expected to benefit from GeneSight. As an important additional analysis – an important additional analysis was performed on the intent-to-treat patient cohort that excluded these patients. . . . Comparing the GeneSight and TAU arms in the patients entering on yellow or red medications, all 3 endpoints were statistically significant with a 70% increase in remission, a 42% improvement in response rates, and a 23% improvement in symptoms. This analysis ***clearly demonstrates that GeneSight improves outcomes for the 70% of patients taking medications that require modification based upon their genetic profile***.

* * *

Capone: As we've noted before in our discussions, those payers really had little to no questions at all about symptom improvements. They were very much focused on remission and response, and they've never seen data whereby remission and response were statistically significantly improved when compared to an active drug arm.

* * *

Capone: One of the other things I can mention because it's working its way to a poster is HAM-D6. There are opinion leaders that believe that HAM-D6 is a more sensitive approach to looking at outcomes compared to HAM-D17, and that data looks exciting.

* * *

Dechairo: One, on the follow-on from GUIDED deeper analyses, we've also -- have seen in sub-analyses that we're putting in posters that the over 65 for Medicare population had even larger magnitude benefits that the whole population had a benefit, and so that's important again with the early data that Medicare already had and made their positive coverage decision before.

266. The foregoing statements by Defendants Capone and Dechairo on January 4, 2019 were materially false and misleading when made because: (i) contrary to Defendants' statements, GeneSight did not show "improvement" in response, remission, or symptom improvement because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (ii) far from demonstrating that "remission and response were statistically significantly improved"

with GeneSight, FDA guidance and standard clinical trial practice make clear that GUIDED's cherry-picked secondary endpoints and improper post-hoc analyses could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (v) far from "clearly demonstrat[ing] that GeneSight improves outcomes for the 70% of patients taking medications that require modification based upon their genetic profile," for example, the results of Myriad's post-hoc subgroup analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized.

267. During the January 4, 2019 Barclays investor call featuring Dr. Nemeroff, Defendant Dechairo misled investors by claiming that, in the GUIDED study data, "on the side effects, we did see in the patients and in the publication a statistically significant impact for patients who were on genetically inappropriate medications on GeneSight, and those that switched off versus those that stayed on. We were significant on side effects as well as symptom improvement response and remission in the group of patients who would benefit the most from pharmacogenomic testing." Dechairo added that "in patients who genetically were identified to be on medications that were inappropriate for them, when basically stopped those medications, we were statistically significant on side effects." After that January 4, 2019 Barclays investor

call, Scott Gleason, head of Myriad's investor relations division, emailed a select number of investors and analysts asserting that Dr. Nemeroff's statements on the Barclay's call were incorrect and inaccurate. Myriad's email stated that Dr. Nemeroff's statement that GeneSight had failed to achieve GUIDED's primary endpoint of statistically significant symptom improvement was "misleading." Myriad countered by stating, "In the PHQ-9 data . . . we achieved statistical significance for symptom improvement." Likewise, Myriad claimed that "Dr. Nemeroff incorrectly stated that there was no difference in side effects between on red medications in the study." Myriad cited its post-hoc congruent/incongruent patient analysis claiming that it showed "a highly statistically significant benefit across all three endpoints" and a statistically significant reduction in side effects for GeneSight patients.

268. The foregoing statements by Myriad on January 4, 2019 were materially false and misleading when made because: (i) far from showing a "highly statistically significant benefit across all three endpoints" and a statistically significant difference in side effects for GeneSight patients, the results of Myriad's post-hoc subgroup analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized; (ii) FDA guidance and standard clinical trial practice makes clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; and (iii) GeneSight did not demonstrate a statistically significant benefit in "the PHQ-9 data" for symptom improvement or any other endpoint; Myriad failed to disclose that multiplicity adjustments required by Myriad's own pre-specified GUIDED Study protocol demonstrated that these results were not statistically significant.

269. On February 5, 2019, during Myriad's second quarter 2019 (the three months ended December 31, 2018) conference call, Defendant Capone once again touted Myriad's

numerous post-hoc analyses of the GUIDED study data, including that the GUIDED study had resulted in statistically significant results in 13 out of 15 endpoints. Capone stated:

> On the Investor Call summarizing the complete dossier, we noted that additional analysis was completed for patients that were Medicare eligible based upon their age when they enrolled in the study. Despite the substantially smaller sample size, the ***results showed statistically significant improvements across all HAM-D17 endpoints at week 8***.
>
> The GeneSight GUIDED patients did numerically better than patients in an optimized active drug arm in all 15 endpoints, with 13 of those endpoints achieving statistical significance and the other 2 approaching significance. There was a preponderance of evidence demonstrating that the population of patients expected to benefit from GeneSight, which was a 70% of patients entering the study on yellow or red medications ***saw significant improvement in outcomes***. And the patients that entered the study on red medications and were switched from those medications ***saw an unprecedented improvement in outcomes***.
>
> As APA guidelines note, the only acceptable outcome for treatment of depression is remission, and ***GeneSight has clearly demonstrated the ability to help physicians achieve this goal***. Moreover, the GUIDED data show that these results were durable and continued to improve over the 24-week study period with remission doubling to 30%.

270. The foregoing statements by Capone on February 5, 2019 were materially false and misleading when made because: (i) GUIDED's prespecified clinical trial protocol specified 65 secondary endpoints, many of which Myriad selectively failed to report; (ii) far from showing "statistically significant improvements across all HAM-D17 endpoints at week 8," "significant improvement in outcomes" and an "unprecedented improvement in outcomes," the results of Myriad's post-hoc subgroup analyses were neither statistically significant nor clinically meaningful, as Myriad's scientists also internally recognized; (ii) FDA guidance and standard clinical trial practice make clear that GUIDED's post-hoc could analyses not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; and (iii) Myriad failed to disclose that multiplicity adjustments required by Myriad's own pre-specified GUIDED study protocol demonstrated that none of the results of its post-hoc analyses were

statistically significant in favor of GeneSight.

271. On March 12, 2019, at the Cowen Healthcare Conference, Defendant Capone again touted the purported statistical significance of the response and remission endpoints: "First, as I already mentioned, one of the key drivers to that was the publication of the GUIDED study that ***showed statistically significant improvements in remission and response which were the two endpoints that were most important to payers***."

272. The foregoing statements by Capone on March 12, 2019 were materially false and misleading when made because: (i) contrary to Defendants' statements, GeneSight did not show "improvements" in response or remission because GeneSight's performance was statistically indistinguishable from "treatment as usual"; (ii) FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; and (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

7. Third Quarter 2019

273. Defendants continued to tout the purportedly favorable results of the GUIDED study. For example, on May 7, 2019, during Myriad's third quarter 2019 earnings call (for the three months ended March 31, 2019), Defendant Capone continued to rely on the results of improper GUIDED study post-hoc subgroup analyses:

> To continue strengthening the dossier, we are publishing data on 2 additional analyses from the GUIDED study. First analysis evaluates the subset of patients that entered the study on medications with gene-drug interactions, which is consistent with the indications for use for GeneSight. GeneSight is indicated for use by physicians contemplating an alteration in neuropsychiatric medications for patients with moderate to severe depression after at least 1 medication failure. Obviously, patients entering this study on green medications are no longer being considered for alterations in their medication. As such, those patients were excluded in this analysis and the patients in the GeneSight arm ***had better outcomes in all 3 clinical endpoints of remission, response and symptom improvement. The results were statistically significan***t.

274. The foregoing statements by Capone on May 7, 2019 were materially false and misleading when made because far from being "statistically significant" or demonstrating that GeneSight patients "had better outcomes," the results of Myriad's post-hoc subgroup analysis were neither statistically significant nor clinically meaningful, as Myriad's own scientists internally recognized.

275. In Myriad's Quarterly Report on Form 10-Q filed with the SEC on May 8, 2019, which reported the Company's financial and operating results for the Company's third quarterly period ended March 31, 2019 (the "3Q 2019 10-Q"), Myriad stated:

> During the quarter ended December 31, 2018, the results of the GeneSight GUIDED study, the largest pharmacogenomics study ever in depression, was accepted for publication in the *Journal of Psychiatric Research*. ***The key finding of the study was that patients were 50 percent more likely to achieve remission and 30 percent more likely to respond to treatment when their medication selection was guided by the GeneSight Psychotropic genetic test***.

276. The foregoing statements by Myriad on May 8, 2019 were materially false and misleading when made because: (i) neither response nor remission were the "key" endpoint of the GUIDED study, but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) FDA guidance and standard clinical trial practice make clear that GUIDED's response and remission endpoints could not even be analyzed, as there was no "demonstration of

a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them.

277. During the May 21, 2019 UBS Global Healthcare Conference, in response to a question from an analyst on how payor coverage would coincide with payors' review of the GUIDED study, Defendant Capone touted the results of Myriad's post-hoc analysis excluding patients on "green medication" as providing "even better, highly statistically significant" results supporting GeneSight's efficacy:

> Specifically, the GUIDED study, the Phase III study, we saw ***statistically significant improvements in remission and response*** . . . . One of the suggestions that was made during the publication of the GUIDED study was that, that analysis should actually be redone in the format of a precision medicine product, which is to look at how GeneSight did in the intended use population, the benefit that is expected -- or the population that is expected to benefit from that. So if you looked at the study, about 30% of the patients that entered this study, were actually already on appropriate medications. So it's a very reasonable ask to look at the performance of GeneSight in the 70% of patients that were expected to benefit from GeneSight and were on medications that had some gene-drug interaction. So that's the additional analysis that's been done. We've provided the top line results to investors for that. That's going to publication now. ***And what that showed is even better results, highly statistically significant results in every endpoint for the GeneSight treated arm***.

278. The foregoing statements by Capone on May 21, 2019 were materially false and misleading when made because: (i) neither response nor remission were primary endpoints of the GUIDED study, but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable;

(ii) far from demonstrating "significant improvements in remission and response" and "even better results, highly statistically significant results," FDA guidance and standard clinical trial practice make clear that neither GUIDED's response and remission endpoints, nor its post-hoc analysis, could even be evaluated, as there was no "demonstration of a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (v) far from being "even better results, highly statistically significant results in every endpoint for the GeneSight treated arm," the results of Myriad's post-hoc analyses were neither statistically significant nor clinically meaningful, as Myriad's own scientists internally recognized.

8. Fourth Quarter 2019

279. On June 11, 2019, at the Goldman Sachs Global Healthcare Conference, Defendant Capone once again touted Myriad's post-hoc analyses of the GUIDED study data, claiming that "[Myriad was] able to provide its additional analysis that [we've] talked to investors about where you look at the 70% of patients that entered this study that are expected to benefit from GeneSight and were able to show statistical significance across all endpoints, including the symptom improvement endpoint."

280. The foregoing statement by Capone on June 11, 2019 was materially false and misleading when made because the results of Myriad's post-hoc analyses were neither statistically significant nor clinically meaningful, as Myriad's own scientists internally recognized.

C. Defendants' False and Misleading Statements and Omissions Concerning Myriad's Interactions with the FDA

281. During the Class Period, Defendants also repeatedly made materially false and misleading statements and omissions concerning Myriad's discussions with the FDA related to GeneSight.

282. On Myriad's November 6, 2018 first fiscal quarter 2019 earnings call (for the three months ended September 30, 2018), held shortly after the FDA issued its Safety Communication raising concerns about the efficacy of pharmacogenomic testing, Capone sought to reassure investors that the supposedly positive results of the GUIDED study would insulate GeneSight from FDA scrutiny. Specifically, Capone stated that the FDA was "***well-aware*** that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has ***clear clinical evidence demonstrating improved patient outcomes***, that that difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing."

283. The foregoing statements by Capone on November 6, 2018 were materially false and misleading when made because, as Capone knew, the FDA had ***never*** indicated to Myriad that it was "well-aware" that GUIDED provided "clear clinical evidence" of GeneSight's efficacy, differentiating it from other pharmacogenomic tests. To the contrary, the GUIDED study was not conducted or reported in accordance with FDA guidance and: (i) neither response nor remission were primary endpoints of the GUIDED study, but Defendants misled investors by touting these two cherry-picked secondary endpoints out of 65 as if they were primary, when, in truth, they were empirically unanalyzable; (ii) far from providing "clear clinical evidence" FDA guidance and standard clinical trial practice make clear that neither GUIDED's response and remission endpoints, nor its post-hoc analyses, could even be evaluated, as there was no "demonstration of

a treatment effect on the primary endpoint family"; (iii) the GUIDED study did not achieve statistical significance on the secondary endpoints of response and remission; Myriad failed to report the results of a multiplicity adjustment (in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the response and remission endpoints in fact lacked statistical significance; (iv) as Myriad scientists internally recognized, neither response nor remission has ever been set as the prespecified primary endpoint of a depression trial and lacked the clinical value Defendants misleadingly ascribed to them; and (v) the results of Myriad's post-hoc analyses were neither statistically significant nor clinically meaningful, as Myriad's own scientists internally recognized. Additionally, as Defendants knew, there was no meaningful clinical evidence supporting the efficacy of GeneSight's ADHD and analgesic panels.

284. Also on Myriad's November 6, 2018 earnings call, Defendant Capone claimed that GeneSight differed from the subjects of the FDA's scrutiny on the basis that, unlike other pharmacogenetic tests, GeneSight's clinical efficacy was supported by clinical evidence:

> Moving on to GeneSight. As many of you are aware the FDA issued a notice for pharmacogenomic testing last week cautioning providers and patients about tests with claims that are not clinically validated. We strongly agree with this position as unlike GeneSight most companies have not published clinical outcomes data supporting their tests. Studies have shown that pharmacogenomic tests are not interchangeable. As an example, a recent study published in the May issue of the Pharmacogenomics Journal compared 4 commercial pharmacogenomics tests for major depressive disorder and found that 19% of the time the test had conflicting clinical recommendations. The FDA has maintained their position to exercise enforcement discretion over LDTs [Laboratory Developed Tests] subject to congressional legislation. Myriad continues to support additional oversight of LDTs through legislation to ensure a consistent level of clinical evidence for approved cleared tests. And we believe that GeneSight is the only pharmacogenomic test supported by level 1 evidence, which demonstrates improved patient outcomes. As a reminder, GeneSight has completed 4 clinical studies, including the 1,200 patient prospective blinded and randomized guided study that ***was conducted consistent with the FDAs guidance on clinical trials for depression***. The GUIDED study compared the GeneSight arm to an active drug arm

> and demonstrated a 50% improvement in symptoms and 30% improvement in response rates, both of which were highly statistically significant, and a 14% improvement in symptoms, which was approaching statistical significance.

285. In addition, months later, during Myriad's January 4, 2019 conference call to announce the publication of the GUIDED study, Defendant Capone described the "***design and rigor of the study [are] similar to studies conducted for a pharmaceutical seeking approval from the FDA***."

286. Moreover, the January 4, 2019 GUIDED medical journal article itself, authored by Defendant Dechairo and others, claimed that "the study design is ***in line with the recent FDA draft guidance for MDD [major depressive disorder] trials***."

287. The foregoing statements by Capone and Dechairo on November 6, 2018 and January 4, 2019 were materially false and misleading when made because the GUIDED study was not conducted or reported in accordance with FDA guidance. Indeed, contrary to FDA guidance, Myriad failed to report the results of a multiplicity adjustment (also in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted in fact lacked statistical significance. Moreover, FDA guidance and standard clinical trial practice make clear that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family."

288. On Myriad's January 4, 2019 conference call announcing the official publication of the GUIDED study, in response to an analyst's question about whether Myriad was a target of the FDA's crackdown on pharmacogenetic tests, Defendant Capone claimed:

> We certainly have – obviously, there's public commentary that's been made, and we've had private discussions as well. I think I mentioned before, we happened to

> be at BioUtah together with Dr. Jeff Shuren [Director of the Center for Devices and Radiological Health at the FDA] on the day that, that actually came out. So I was there with him. Dr. Shuren was the keynote speaker there. And so we were there and got a chance to catch up on a number of topics that we discussed over the years. What I can say is they have always publicly differentiated between consumer testing and LDTs [Laboratory Developed Tests]. As you well know, there were efforts made a few years ago specifically to crack down on consumer testing. That's testing done on a more recreational basis without having health-care professionals involved. That has always been a significant concern for the agency, and I think that remains a concern for the agency that -- that is an area that they're concerned about how -- what the impact to patients could be for direct-to-consumer types of testing. ***Obviously, we're in a very different space.*** . . So I know there is a very clear distinction in the line, and I think that distinction remains.

289. The foregoing statements by Capone on January 4, 2019 were materially false and misleading when made because they portrayed Myriad as somehow outside the scope of the FDA's scrutiny of pharmacogenomic testing and misstated and failed to disclose that GeneSight lacked evidence sufficient to support the test in its current form, including the purported benefits of its ADHD, analgesic, and psychotropic panels. Moreover, (i) contrary to FDA guidance, Myriad failed to report the results of a multiplicity adjustment of the GUIDED data (also in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted in fact lacked statistical significance; (ii) FDA guidance and standard clinical trial practice make clear that the cherry-picked secondary endpoints and post-hoc analyses of the GUIDED data Defendants touted could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family."

290. On May 7, 2019, during Myriad's third quarter 2019 earnings call, in response to an analyst question about Myriad's ongoing conversations with the FDA, Defendant Capone acknowledged that Myriad had in fact previously sent data to the FDA regarding GeneSight without disclosing the full truth about the FDA's inquiry into Myriad:

> Yes. Thanks, Jack. I'd just refer back to the comments I think I made on the last call that serendipitously, I was actually at a conference with Dr. Jeff Shuren the day that 23andMe got clearance for their test, which, of course, was the other thing that came along that with that was the posting of the commentary from the FDA on their website and so we had a chance to talk at that point. It's not clear they were actually aware of GeneSight then. And so I brought Dr. Shuren up to speed on the product, did in fact acknowledge that we would have a publication coming out relatively shortly and that I would send a copy of that manuscript if they were interested. And so that's what we've done is mailed that to them. And so they have that manuscript. So to date, that's really any of the discussions have really been largely that. It's just us following up on sending them over that publication.

291. The foregoing statements by Capone on May 7, 2019 were materially false and misleading when made because they misstated and failed to disclose that GeneSight lacked evidence sufficient to support the test in its current form, including the purported benefits of its ADHD, analgesic, and psychotropic panels. Moreover, (i) contrary to FDA guidance, Myriad failed to report the results of a multiplicity adjustment of the GUIDED data (also in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted in fact lacked statistical significance; (ii) FDA guidance and standard clinical trial practice make clear that the cherry-picked secondary endpoints and post-hoc analyses of the GUIDED data Defendants touted could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family." Additionally, the FDA was investigating the validity of the test's purported benefits, had expressed serious concerns to Myriad about GeneSight's efficacy, and had requested that Myriad make commercially devastating changes to the product.

292. On May 15, 2019, during the Bank of America Merrill Lynch Health Care Conference, in response to an analyst question regarding the "competitive dynamics of GeneSight," Defendant Riggsbee differentiated GeneSight from competing products by asking attendees to "look at the clinical studies that we've performed, I think that's another area we get

questions from time to time from folks that are looking at FDA and other agencies and their interests in these tests. And I think that's the difference between if you look at some of the commentary out there, it's really focused on the tests that are well validated from a clinical scientific standpoint. And when you look at the large study that we had in GUIDED, we have the data out there that really is what separates us and what will make the test quite frankly more durable over time."

293. The foregoing statements by Riggsbee on May 15, 2019 were materially false and misleading when made because they misstated that the GUIDED trial differentiated GeneSight from its competitors and "validated" GeneSight "from a clinical scientific standpoint" when, in reality, it was a failed trial. Riggsbee also failed to disclose that GeneSight lacked evidence sufficient to support the test in its current form, including the purported benefits of its ADHD, analgesic, and psychotropic panels. Moreover, (i) contrary to FDA guidance, Myriad failed to report the results of a multiplicity adjustment of the GUIDED data (also in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted in fact lacked statistical significance; (ii) FDA guidance and standard clinical trial practice make clear that the cherry-picked secondary endpoints and post-hoc analyses of the GUIDED data Defendants touted could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family." Additionally, the FDA was investigating the validity of the test's purported benefits, had expressed serious concerns to Myriad about GeneSight's efficacy, and had requested that Myriad make commercially devastating changes to the product.

294. On June 11, 2019, at the Goldman Sachs Global Healthcare Conference, Defendant Capone once again sought to assuage investors by differentiating GeneSight from its competition

being targeted by the FDA:

> Again as the only company that has done a large prospect[ive] Phase III study and also 3 Phase II studies, all of which have demonstrated improved patient outcomes, we're the only company that actually has done that. From our perspective, we pointed out to the agency that we do in fact have data on our specific tests, and that was the dialogue I had is that, I think, when that initial posting came out in November, guided wasn't published. So I just made the FDA aware that there will be -- that there was going to be validation data published, and we, of course, made that available and volunteered to send that to the agency when it was published in January.

295. The foregoing statements by Capone on June 11, 2019 were materially false and misleading when made because they misstated that the GUIDED trial differentiated GeneSight from its competitors and "demonstrated improved patient outcomes" when, in reality, it was a failed trial. Capone also failed to disclose that GeneSight lacked evidence sufficient to support the test in its current form, including the purported benefits of its ADHD, analgesic, and psychotropic panels. Moreover, (i) contrary to FDA guidance, Myriad failed to report the results of a multiplicity adjustment of the GUIDED data (also in violation of Myriad's own pre-specified GUIDED study protocol), which would have demonstrated to investors that the cherry-picked secondary endpoints and post-hoc analyses Defendants touted in fact lacked statistical significance; (ii) FDA guidance and standard clinical trial practice make clear that the cherry-picked secondary endpoints and post-hoc analyses of the GUIDED data Defendants touted could not even be analyzed, as there was no "demonstration of a treatment effect on the primary endpoint family." Additionally, the FDA was investigating the validity of the test's purported benefits, had expressed serious concerns to Myriad about GeneSight's efficacy, and had requested that Myriad make commercially devastating changes to the product.

D. Defendants' False and Misleading Statements and Omissions Concerning Myriad's Hereditary Cancer Test Revenue

296. As Myriad only disclosed on November 4, 2019, Myriad knowingly or recklessly

overstated revenue attributable to its hereditary cancer test during the Class Period, which rendered its prior statements concerning hereditary cancer test revenue materially false and misleading.

297. On May 7, 2019, Myriad's Form 8-K filed with the SEC and signed by Defendant Riggsbee contained both an earnings release and an earnings call slide presentation for the three and nine months ended March 31, 2019 (*i.e.*, the third fiscal quarter of 2019). Both the earnings release and earnings call slide reported hereditary cancer test revenue for the three months ended March 31, 2019 of $117.6 million.

298. On May 8, 2019, Myriad filed with the SEC a Form 10-Q that was signed by Defendants Capone and Riggsbee. The Form 10-Q also reported hereditary cancer revenue for the three months ended March 31, 2019 of $117.6 million. In addition, the May 8, 2019 Form 10-Q claimed that "The accompanying condensed consolidated financial statements have been prepared by Myriad Genetics, Inc. (the 'Company' or 'Myriad') in accordance with U.S. generally accepted accounting principles ('GAAP') for interim financial information and pursuant to the applicable rules and regulations of the Securities and Exchange Commission ('SEC')."

299. On August 13, 2019, during Myriad's fiscal fourth quarter 2019 (for the three months ended June 30, 2019) earnings call, Defendant Riggsbee claimed "Hereditary cancer revenue" during the quarter in the amount of "$119 million, which was up 1% on a sequential basis due to increased volumes." Also on August 13, 2019, Myriad filed a Form 8-K with the SEC that was signed by Defendant Riggsbee. The Form 8-K contained both an earnings release and an earnings call slide presentation dated August 13, 2019 for the three and nine months ended June 30, 2019, which reported hereditary cancer revenue for the three months ended June 30, 2019 of $119 million. That same day, Myriad also filed a Form 10-K with the SEC that was

signed by Defendants Capone and Riggsbee. The Form 10-K, which reported hereditary cancer revenue for the fiscal year ended June 30, 2019 of $479.7 million, claimed that "The accompanying consolidated financial statements have been prepared by Myriad Genetics, Inc. (the 'Company' or 'Myriad') in accordance with U.S. generally accepted accounting principles ('GAAP') for financial information and pursuant to the applicable rules and regulations of the Securities and Exchange Commission ('SEC')."

300. Myriad's reported hereditary cancer test revenue in the third and fourth quarters of fiscal year 2019 were materially false and misleading because, as Myriad later admitted, Myriad overstated its reported hereditary cancer revenue during the third and fourth quarters of fiscal year 2019 by at least $18 million. This amount was material, including because, absent the over-statement, Myriad's income before income tax in the third quarter of fiscal year 2019 would have been a loss instead of a profit. In addition, the overstatement during the third and fourth quarters of fiscal year 2019 overstated to investors Myriad's financial prospects going forward because the overstatement hid from investors that the correct revenue accrual model for Myriad would result in a decreased revenue amount. Furthermore, as set forth above, Myriad's claims that the reporting of its third and fourth quarter fiscal year 2019 hereditary cancer test revenue amounts was prepared in accordance with GAAP were materially false and misleading because such reporting violated GAAP.

301. In addition, Defendants Capone and Riggsbee signed certifications pursuant to the Sarbanes-Oxley Act, appended to Myriad's third quarter 2019 (three months ended March 31, 2019) Form 10-Q, filed May 8, 2019, and its 2019 Form 10-K (for the year ended June 30, 2019), filed August 13, 2019. In these certifications, Defendants Capone and Riggsbee attested that they personally "evaluated the effectiveness of [Myriad's] disclosure controls and procedures" and

> Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
>
> Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

302. Defendants' statements were materially false and misleading when made because the SEC filings to which these certifications were appended failed to disclose that Myriad had overstated its hereditary cancer revenue, which had been reported in violation of GAAP and that Myriad was improperly recognizing hereditary cancer test revenue on the assumptions that (i) payors would consent, without question, to the Company's unilateral decision to replace its obsolesced billing codes with the most expensive alternative; and (ii) the significant increase in denied and short-paid claims would reverse itself.

303. Defendants also made claims to investors from the third and fourth quarters of fiscal 2019 going forward that misstated and hid from investors Myriad's difficulties with hereditary cancer test reimbursement and its misstatement of hereditary cancer test revenues. For example:

- On February 5, 2019, during Myriad's second quarter 2019 (the three months ended December 31, 2018) earnings call, an analyst asked Defendant Riggsbee about how Myriad had **"**reiterated guidance, but, obviously, we've had a few puts and takes with GeneSight" and asked "Should we assume that the overall GeneSight number for the year is going to be down relative to your initial expectations that's being made up for and things like hereditary cancer?" In response, Riggsbee claimed, "I think what I would say in terms of the back half of the year, we continue to be very pleased with our Hereditary Cancer business and the way that business has performed";

- On February 5, 2019, Defendant Capone lauded the Company's success in turning around its hereditary cancer test franchise, claiming "We delivered strong hereditary cancer results this quarter as year-over-year pricing headwinds abated and volume growth continued with total Hereditary Cancer revenue increasing 4% year-over-year and 9% sequentially";

- Also on February 5, 2019, and in response to a question from an analyst concerning Myriad's hereditary cancer billing practices, Capone stated that: "We've already made comments a year or so ago on how we've approached the billing for hereditary cancer testing and nothing has really changed from that perspective. Of course, the only thing was the uncertainty around next-generation sequencing and where that fits. So I think, we're just going to have to see how this resolves itself as the industry engages";

- On May 7, 2019, in a Form 8-K that Myriad filed with the SEC, Myriad touted that hereditary cancer test "revenue growth reached four percent, the highest in the last five fiscal years" and claimed that the Company had "[a]chieved [its] . . . sixth consecutive quarter with stable hereditary cancer pricing";

- On May 7, 2019, during Myriad's third quarter fiscal 2019 (the three months ended March 31, 2019) earnings call, Capone continued to profess that Myriad had turned around its hereditary cancer segment. In his words, "The hereditary cancer business has returned to growth for 2 consecutive quarters and we are expecting stable revenue in fiscal year 2020";

- On the same May 7, 2019 call, Capone continued: "Revenue in the third quarter was $216.6 million, which met expectations as a result of continued year-over-year growth in hereditary cancer revenue and 51% new product volume growth." Defendant Riggsbee also added that: "Hereditary cancer revenue in the quarter of $117.6 million was up 4% compared to $113.1 million reported in the third quarter of fiscal year 2018." Specifically, in providing guidance on hereditary cancer pricing, Riggsbee claimed that "[w]e have made substantial progress with the hereditary cancer payer contracts, and as a result are anticipating that hereditary cancer revenues in fiscal 2020 will be relatively flat compared to fiscal 2019 as increasing volumes will offset very modest anticipated price declines";

- On May 15, 2019, at the Bank of America Merrill Lynch Healthcare Conference, Defendant Riggsbee continued to project stable, or flat hereditary cancer revenue: "So what we -- the comment that we had made on the call was that we would expect to see basically flat revenue for hereditary cancer in fiscal year 2020 with some growing -- growth in volume offsetting some modest price declines";

- On May 21, 2019, at the UBS Global Healthcare Conference, an analyst asked Defendant Capone the following question about the hereditary cancer testing pricing pressure and GeneSight's general financial performance: "Just maybe starting with hereditary cancer. I mean, the stock prices come off pretty materially since the quarter. I'm just wondering, as I look through some of the commentary there, possibly it was the indication that pricing might come down slightly. There was a lot of nuance around that. Maybe you can just step back and kind of think about how the quarter came in versus the way management thought about it, and then kind of your guidance, how that's been received?" Defendant Capone responded: "So I think, overall, we were pleased with the quarter. It was in line with our expectations. In fact, if you actually looked at it from a profitability

standpoint, it was ahead of expectations. So overall, I think we felt like it was in line on the revenue side, a beat on the earnings side. That was our take on that. And when you're growing revenue 18% and earnings 35%, I would say that's not a bad quarter";

- On June 11, 2019 at the Goldman Sachs Global Healthcare Conference, Defendant Capone was asked about whether there are pricing pressures that will jeopardize the Company's hereditary cancer test revenues and Capone once again forecasted "flat" hereditary cancer revenues, and responded, "I think, big picture, we'd say, actually, if you look at flat hereditary cancer revenue in fiscal '20, that actually exceeded what the analyst numbers were for fiscal year '20. So I'll just make a note on that. What we've been able to do in the last year or so is to renew or continue a substantial number of our long-term contracts. And as a result of that, we're able to get visibility into pricing in fiscal year '20"; and

- On September 10, 2019, at the Morgan Stanley Healthcare Conference, analysts once again asked Defendant Capone whether he could discuss his guidance for the flat hereditary cancer revenue in fiscal 2020, to which Defendant Capone reiterated that "[t]his year we guided to relatively flat hereditary cancer revenues. And in that, we are anticipating modest volume growth being offset by modest price reduction. So that's the guidance we've provided for fiscal year '20."

304. The foregoing statements by Defendants Myriad, Capone and Riggsbee were materially false and misleading because they failed to disclose that, in violation of GAAP, Myriad was improperly recognizing hereditary cancer test revenue on the assumptions that (i) payors would consent, without question, to the Company's unilateral decision to replace its obsolesced billing codes with the most expensive alternative; (ii) the significant increase in denied and short-paid claims would reverse itself; and (iii) Myriad had overstated its hereditary cancer test revenue.

VII. CLASS ACTION ALLEGATIONS

305. Los Angeles brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Myriad common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in

which Defendants have or had a controlling interest.

306. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Myriad common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Los Angeles at this time and can be ascertained only through appropriate discovery, Los Angeles believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Myriad or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

307. Los Angeles's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

308. Los Angeles will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation. Los Angeles has no interests antagonistic to or in conflict with those of the Class.

309. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and finances of Myriad;
- whether the Individual Defendants caused Myriad to issue false and misleading statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of Myriad common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

310. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

311. Los Angeles will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Myriad common stock is traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Los Angeles and members of the Class purchased, acquired and/or sold Myriad common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

312. Based upon the foregoing, Los Angeles and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

313. Alternatively, Los Angeles and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I
(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

314. Los Angeles repeats and re-alleges each and every allegation contained above as if fully set forth herein.

315. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

316. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Los Angeles and the other members of the Class. This course of conduct included, as set forth above in ¶¶43-304, the making of various untrue statements of material facts and omission to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and the employment of devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Los Angeles and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Myriad common stock; and (iii) cause Los Angeles and other members of the Class to purchase or

otherwise acquire Myriad common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

317. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Myriad common stock. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Myriad's finances and business prospects.

318. By virtue of their positions at Myriad, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Los Angeles and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

319. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Myriad, the Individual Defendants had knowledge of the details of Myriad's internal affairs.

320. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Myriad. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Myriad's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Myriad common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Myriad's business and financial condition which were concealed by Defendants, Los Angeles and the other members of the Class purchased or otherwise acquired Myriad common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

321. During the Class Period, Myriad common stock was traded on an active and efficient market. Los Angeles and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Myriad common stock at prices artificially inflated by Defendants' wrongful conduct. Had Los Angeles and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Los Angeles and the Class, the true value of Myriad common stock was substantially lower than the prices paid by Los Angeles and the other members of the Class. The market price of Myriad common stock

declined sharply upon public disclosure of the facts alleged herein to the injury of Los Angeles and Class members.

322. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

323. As a direct and proximate result of Defendants' wrongful conduct, Los Angeles and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating false and misleading information to the investing public.

COUNT II
(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

324. Los Angeles repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

325. During the Class Period, the Individual Defendants participated in the operation and management of Myriad, and conducted and participated, directly and indirectly, in the conduct of Myriad's business affairs. Because of their senior positions, they knew the adverse non-public information about Myriad's business, operations, and finances.

326. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Myriad's financial condition and results of operations, and to correct promptly any public statements issued by Myriad which had become materially false or misleading.

327. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public statements which Myriad disseminated in the marketplace during the Class Period concerning Myriad's results of business, operations, and finances. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Myriad to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Myriad within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Myriad common stock.

328. Each of the Individual Defendants, therefore, acted as a controlling person of Myriad. By reason of their senior management positions of Myriad, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Myriad to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Myriad and possessed the power to control the specific activities which comprise the primary violations about which Los Angeles and the other members of the Class complain.

329. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Myriad.

COUNT III
(Violations of Section 10(b) and 20A of the Exchange Act and Rule 10b-5 Promulgated Thereunder for Insider Trading Against Defendants Capone and Riggsbee)

330. This Count is asserted for violations of Section 20A of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of Los Angeles and all other members of the Class who purchased shares of Myriad common stock contemporaneously with the sale of Myriad common stock by

Defendants Capone and Riggsbee while they were in possession of material, nonpublic information as alleged herein, including concerning Myriad's GeneSight test, the GUIDED study, and the Company's hereditary cancer test revenue.

331. Section 20A of the Exchange Act provides that "[a]ny person who violates any provision of the [Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased securities of the same class."

332. As set forth herein, Defendants Capone and Riggsbee violated Exchange Act Section 10(b), Rule 10b-5 and Section 20(a) for the reasons stated in Counts I and II above. Additionally, Defendants Riggsbee and Capone further violated Exchange Act Section 10(b), Rule 10b-5, and Rule 10b5-1 (17 C.F.R. § 240.10b5-1) by selling shares of Myriad common stock while in possession of material, nonpublic adverse information concerning Myriad's GeneSight test, the GUIDED study, and the Company's hereditary cancer test revenue, which information they had a duty to disclose, and which they failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein.

333. Contemporaneously with Defendant Capone's sale of 80,000 shares of Myriad common stock on July 11, 2018 (for proceeds of more than $3.2 million), Los Angeles purchased at least 13,486 shares of Myriad common stock, on July 13, 2018, on a national securities exchange, while Defendants were in possession of material, nonpublic information they had a duty to disclose, but failed to disclose, as alleged herein, including information concerning Myriad's GeneSight test, the GUIDED study, and the Company's hereditary cancer test revenue.

334. Other Class members also purchased shares of Myriad common stock contemporaneously with Defendants' sales of Myriad common stock.

335. Los Angeles and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

336. By reason of the violations of the Exchange Act alleged herein, Defendants Capone and Riggsbee are liable to Los Angeles and other members of the Class who purchased shares of Myriad common stock contemporaneously with Defendants' sales of Myriad common stock during the Class Period.

337. Los Angeles and the other members of the Class who purchased contemporaneously with Defendants' sales of Myriad common stock sales seek disgorgement by Defendants Capone and Riggsbee of profits gained or losses avoided from their transactions in Myriad common stock contemporaneous with Los Angeles and other members of the Class.

338. This action was brought within five years after the date of the last transaction that is the subject of the Defendant Capone's and Defendant Riggsbee's violations of Section 20A, and, with respect to the underlying violations of Section 10(b) of the Exchange Act alleged in this Count and in Count One above, was brought within five years after the date of the last transaction that violated section 20A of the Exchange Act by Defendants Capone and Riggsbee.

VIII. PRAYER FOR RELIEF

WHEREFORE, Los Angeles demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Los Angeles as the Class representative;

B. Requiring Defendants to pay damages sustained by Los Angeles and the Class by reason of the acts and transactions alleged herein;

C. Awarding Los Angeles and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

IX. DEMAND FOR TRIAL BY JURY

Los Angeles hereby demands a trial by jury.

Dated: February 21, 2020

Respectfully submitted,

s/ Salvatore Graziano
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CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2020, I electronically filed the foregoing Amended Class Action Complaint with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all attorneys on record.

/s/ Salvatore Graziano
Salvatore Graziano